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TITLE: Conformational Radiation by Brachytherapy in Prostate Cancer; The Establishment of an RTOG 3-D Evaluation Center for Multi-Institutional Studies

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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13. ABSTRACT ***(Maximum 200 Words)***

The work funded by this grant was used to establish credentialing requirements and quality assurance (QA) guidelines for the conduct of national, multi- institutional cooperative group studies of Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB). A methodology for electronic data exchange of TIPPB treatment planning verification data between institutions participating in a future TIPPB protocol and the 3DQA Center at Washington University in St. Louis has been developed. In addition, the 3DQA Center has developed a credentialing process and QA guidelines to ensure that participating institutions have the proper equipment and appropriate procedures in place to administer TIPPB. A 3D radiation treatment planning (3DRTP) system has been adapted to serve as a 3DQA review station of clinical and dosimetric data for patients entered on Radiation Therapy Oncology Group (RTOG) and other cooperative group TIPPB protocols. Remote review software tools that allow centralized QA and dose evaluation have been developed. A database for the TIPPB treatment planning data that can be linked with clinical outcome data has been developed.

14. SUBJECT TERMS
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INTRODUCTION

Although local treatment of early prostate cancer by external beam radiation therapy or surgery has been somewhat successful, local recurrence, metastases and the morbidity of treatment remain substantial problems limiting the complication-free cure rate of this very common disease. Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) is being selected by a rapidly increasing proportion of patients as the solution to the problems associated with radiation therapy and surgery. TIPPB is technically challenging. Achieving a tumorcidal dose throughout the entire gland is believed to be an important goal in total tumor eradication (TTE) and in practice is difficult to achieve. Although the procedure has shown good results in the hands of experienced teams, there remains no accepted credentialing or certification process for the many inexperienced clinicians beginning to perform TIPPB. This funded effort was designed to address this need in anticipation of future prospective multi-institutional clinical trials.

Specifically, over the course of this grant (Sep 1998-Feb 28, 2001), the 3D Quality Assurance (3DQA) Center at Washington University School of Medicine located in St. Louis, Missouri in association with the Radiation Therapy Oncology Group (RTOG) proposed to complete the 5 tasks listed below:

Task 1. Develop and evaluate analytical methods and tools for three-dimensional calculation and dose volume histogram evaluation of prostate brachytherapy (months 1-24).
   a. Review published recommendations, data from RTOG 98-05, data from any multi-institutional pilot studies, and other data sets to determine current standards of care.
   b. Implement 3D dose calculation and dose volume histogram evaluation tool for prostate brachytherapy.
   c. Establish a set of parameters, which can be effectively used to quantify implant quality.
   d. Test the proposed criteria against sample data from RTOG 98-05 as well as other data sources.
   e. Evaluate commercial systems as to their ability to provide a similar or enhanced analysis.

Task 2. Establish a methodology for electronic data exchange of treatment planning verification data between institutions and the 3DQA Center as well as the RTOG Statistical Headquarters (months 1-18).
   a. Use existing 3DQA Center and RTOG expertise to develop file formats and transfer protocols similar to those currently used by the 3DQA Center, but appropriate for prostate brachytherapy.
   b. Publish data exchange protocol specification.
   c. Conduct data transfer testing at the appropriate institutions to verify electronic transfer protocol structure.
   d. Work with the various TIPPB treatment planning system vendors to implement this data exchange specification as has been done with the 3D CRT external beam data exchange.

Task 3. Develop a program for providing centralized quality assurance reviews of treatment planning verification data which would be submitted by participating institutions for patients receiving TIPPB as part of any future prospective, multi-institutional research trials. (months 1-30)
   a. Develop and implement WWW-based graphical review tools to facilitate remote QA review of patient images, organ contours, 2-D dose distribution, and dose-volume histograms (DVHs) of pre-plan results and, from post-implant imaging, review of the dosimetric quality of each implant.
   b. Develop and implement electronic notification procedure from 3DQA Center to the participating institution of results of pre-plan analysis and post-implant evaluation.

Task 4. Develop guidelines for the credentialing of institutions enrolled in national prostate brachytherapy trials and establish QA standards for the performance of TIPPB. (months 1-30)
   a. Develop a facility questionnaire documenting capability to perform TIPPB. (months 1-3)
   b. Design and test a "Dry-Run Test" which each participant must complete to insure that each participant can successfully plan and calculate a simple, geometrically-defined prostate implant. (months 18 and 30)
   c. Review the appropriateness of the quality assurance criteria. (months 18 and 30)
   d. Publish revised standards for appropriateness of implant quality (months 18 and 30).

Task 5. Develop a dosimetric database to be used in the correlation of implant quality with efficacy of tumor eradication and morbidity of the procedure (months 3-30).
   a. Develop the database structure appropriate for TIPPB within the current RTOG dosimetry database system (months 3-6).
   b. Implement and test the structure (months 6-24).
   c. Periodically evaluate the database for procedural trends and the appropriateness of dosimetric guidelines and quantifiers (months 6-30).

BODY

In this section, we describe the research accomplishments associated with each Task outlined in the approved Statement of Work.

Task 1. Develop and evaluate analytical methods and tools for three-dimensional calculation and dose volume histogram evaluation of prostate brachytherapy (months 1-24).

The 3DQA Center currently uses an in-house developed three-dimensional Radiation Treatment Planning (3DRTP) system that we call "MIR3D" as the QA review station for external beam protocol data submissions. Funding from this grant was used to convert a commercially available 3DRTP system (Computerized Medical System, Inc. (CMS) FOCUS) into a TIPPB QA review station that can be used for on-site QA reviews, i.e., at the 3DQA Center. The 3DQA

Center was a co-developer of this system and thus has access to source code allowing modifications pertinent to QA review functions. The advantage to this conversion was the fact that FOCUS already included support for brachytherapy objects and displays, which the MIR3D based QA review station did not. It would have required significantly more development effort to implement those brachytherapy dose calculation, display, and evaluation features on MIR3D as compared to porting the RTOG Data Exchange to FOCUS (see next task) and using the existing brachytherapy features. The FOCUS QA review station provides dose calculation and isodose display for TIPPB plan QA review. Isodose lines can be displayed on selected CT images and on 3D structures for patient anatomy and target volumes. In addition, the FOCUS QA review station provides for dose-volume histogram (DVH) calculations and display for TIPPB plan QA review.

In summary, an advanced QA review system is now in place that provides software tools for 3-D calculation and dose volume histogram analytical evaluation of TIPPB.

Task 2. Establish a methodology for electronic data exchange of treatment planning verification data between institutions and the 3DQA Center as well as the RTOG Statistical Headquarters (months 1-18).

The 3DQACenter-Washington University School of Medicine has established a standard for the submission of digital data to the 3DQA Center for central review (**RTOG Data Exchange Specification for Tape/Network Format for Exchange of Treatment Planning Information)** [1]. This grant helped fund the developmental effort required to change the standard to accommodate TIPPB protocol digital data submission. Detailed information can be obtained from the 3DQA Center's web page [2]. Briefly, the additional data types needed to support TIPPB protocols are: ultrasound (US) images, magnetic resonance (MR) images, and brachytherapy seed plans. US images and MR images data exchange issues are very similar to those posed by the already implemented computed tomography (CT) image data exchange. The "Seed Plan" data type adds the following directory keywords: SEED MODEL, ISOTOPE, SEED STRENGTH, STRENGTH UNITS, DATE OF IMPLANT, and NUMBER OF SEEDS. The data file for "Seed Plan" consists of the spatial coordinates of the seeds. The 3DQACenter-Washington University School of Medicine has implemented this standard and is now able to read TIPPB plans in anticipation of multi-institutional protocol(s) that will be developed in the near future.

To review briefly, a data exchange submission consists of a set of files. The first file in the file set is a "directory file" describing all of the other "data files". The directory file consists of keyword and keyvalue pairs describing the data files contained in the submission. Figure 1 shows a block diagram of the process of preparing a submission of a protocol data set to the 3DQA Center.

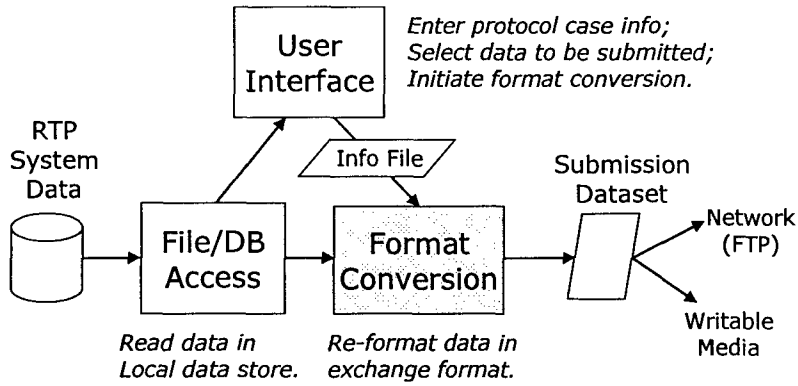

Figure 1: Block diagram of digital data submission.

We recognize that electronic data submission for protocol patients is laborious in the current implementation on most image-based planning systems. Continued work in the area of data exchange by the treatment planning system manufacturers is needed, and users are being encouraged to contact the manufacturer of their treatment planning system to request improved system features that will simplify the data submission process.

The 3DQA Center has held two workshops in the past on the implementation of the RTOG Data Exchange Specification. Specific to this grant funding period, the 3DQA Center held a 2-day technical workshop on September 10, 1999 from 11:00 AM to 5:00 P.M. and September 11, 1999 from 8:30 AM to 3:00 PM at the Mallinckrodt Institute of Radiology Radiation Oncology Center in St. Louis, MO. Representatives of several commercial radiation treatment planning (RTP) system manufacturers attended the workshop. The workshop was aimed at the RTP software developer with the goal of this workshop being:

- to present a complete review of the draft version of the ***Specification*** including the recent brachytherapy additions;
- to highlight specific issues pertaining to the information required by the ***Specification*** and review the 3DQA Center requirements beyond the basics of the data exchange;
- to discuss implementation methods and demonstrate a functioning, clinical prototype implementation of the ***Specification*** for writing exchange data files;
- to provide sample source code, written in C, to assist in the implementation of data file generation required by this data exchange.

At the workshop the draft specification was modified and finalized by the workshop participants and the 3DQA Center staff. V4.00, which includes support for TIPPB protocols, is now the current specification. **(See Appendix 1)**.

Please note that it is the 3DQA Center's intention to move toward a complete implementation of the RT-DICOM data objects necessary to support TIPPB trials over the next six to twelve months. During this time we are optimistic that the treatment planning system vendors will implement complementary capabilities to support such trials and we will be assisting them in appropriate object compliance selections to ensure that the RTOG Data Exchange may ultimately

be retired. However, in order to keep the current external beam 3DCRT studies active, as well as to not hinder the newly proposed intensity modulated radiation therapy (IMRT) and TIPPB studies, the RTOG Patient Data Exchange will continue to be the medium of exchange until both the 3DQA Center and treatment planning system manufacturers can both provide a RT-DICOM solution.

One RTP vendor (CMS) has completed the implementation of the WRITE of RTOG Data Exchange (v4.00) for TIPPB as evidenced by a user submitting a data set for review. However, it should be noted that the FOCUS system does not support image-based pre-plans that may be required by TIPPB protocols.

Varian Medical Systems (MMS RTP system) verbally committed to completing the RTOG format implementation by October 2000, but that commitment deadline has slipped significantly with no projected date of implementation. Varian recently identified their desire to use their DICOM implementation for participation, but acknowledged that they had not yet incorporated any of the RT objects in their implementation.

Prowess Systems/SSGI (Prowess RTP system) indicated that they had begun implementation of the RTOG output format in mid-July, 2000. However, while design has been performed, no implementation has actually begun and no timeline has been established for implementation. They also have not implemented all the required objects in their DICOM software to support a multi-institutional TIPPB trial at this point in time.

It is clear from recent conversations between 3DQA Center and representatives of both Varian and Prowess/SSGI that neither vendor is likely to implement the RTOG data exchange any time soon. Additionally, while these companies express their desire to use their "existing" DICOM software to support TIPPB multi-institutional trials, neither has a complete implementation necessary and at least one of their representatives suggested a "quasi-DICOM" format to support permanent implants which would be neither DICOM or RTOG. Thus, unless there is sufficient pressure applied by the radiation oncology community (treatment planning system users), National Cancer Institute (NCI), and RTOG on these two companies (who are the two major commercial entities involved in TIPPB treatment planning), it remains problematic to have the necessary software in place to provide for digital data exchange, and thus centralized quality assurance for multi-institutional TIPPB trials.

In summary, we have successfully completed our goal to establish a methodology for electronic data exchange of TIPPB treatment planning verification data between institutions and the 3DQA Center as well as the RTOG Statistical Headquarters. However, until a sufficient number of RTP vendors implement TIPPB data exchange capabilities on their planning systems, multi-institutional TIPPB clinical trials requiring digital data submission remain problematic. A positive development is that the 3DQA Center has a DICOM 3.0 workshop scheduled for March 16-17, 2001 (outside of this grant's funding period) at which both Prowess Systems/SSGI and Varian Medical Systems (MMS) have registered to attend. This suggests that they are serious about supporting multi-institutional trials work through implementation of standardized data exchange and that the major limitation on multi-institutional TIPPB clinical trials may soon be removed.

Task 3. Develop a program for providing centralized quality assurance reviews of treatment planning verification data which would be submitted by participating institutions for patients receiving TIPPB as part of any future prospective, multi-institutional research trials. (months 1-30)

Funds from this grant were used to partially support the software developmental of WWW-based graphical review tools to facilitate centralized QA and dose evaluation of TIPPB treatment plans at locations remote from the 3DQA Center. Specific remote review tools include patient CT images, organ contours displayed on selected CT images, isodose lines displayed on selected CT images, and dose-volume histograms for selected target volumes and organs at risk. An example of one of our remote review displays is shown in Figure 2.

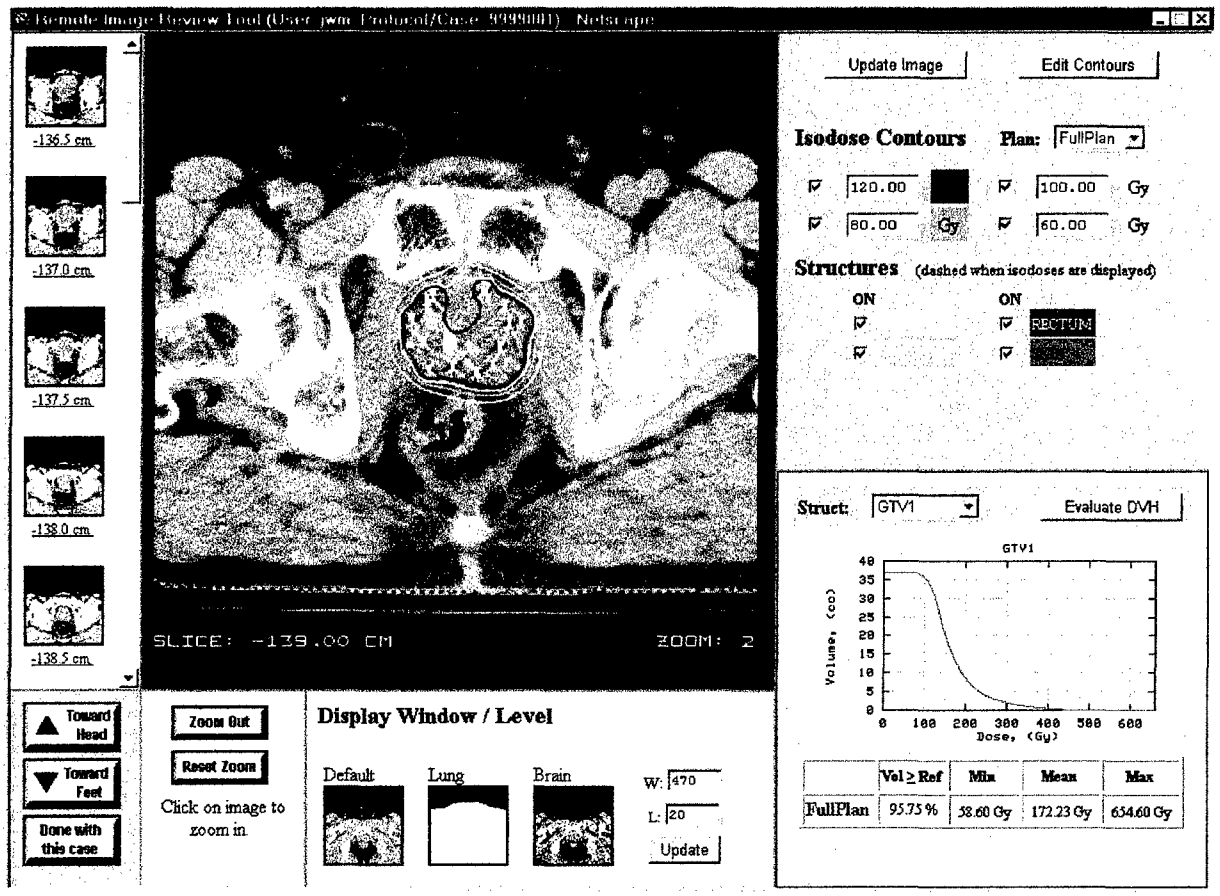

Figure 2. WWW-based Graphical Review Tool

The web-based tools include applets that provide rapid local interaction. Two of the applet based tools that are appropriate for TIPPB review are: 1) a contouring tool and 2) a DVH analysis tool. These tools were written in the JAVA programming language. In order to facilitate this development, Dr. Matthews attended a course at the "Center for the Application of Information Technology" (CAIT) at Washington University. The course was titled "Java Programming Workshop: part 2". A brief description of the two applets is given below.

- *Contouring Applet*: This applet allows reviewers to add contours for structures or targets. Any contours that the reviewer may add are kept in a separate data base area (per reviewer) until approved for addition to the QA database.

- *DVH Analysis Applet*: This applet allows a reviewer to see a magnified version of the DVH shown in the lower right of Figure 2 and to make specific measurements from the curve(s). The magnified view fills the window normally occupied by the image. The user can either pick points off with the cursor interactively or type values and get the corresponding values.

When the Java applets are used, they replace the main display window in the remote review tool shown in Figure 2. Figure 3 shows the two applets. On the left, the contouring applet is shown with a contour that has been added for the left femur. On the right, the DVH analysis applet is illustrated for GTV1.

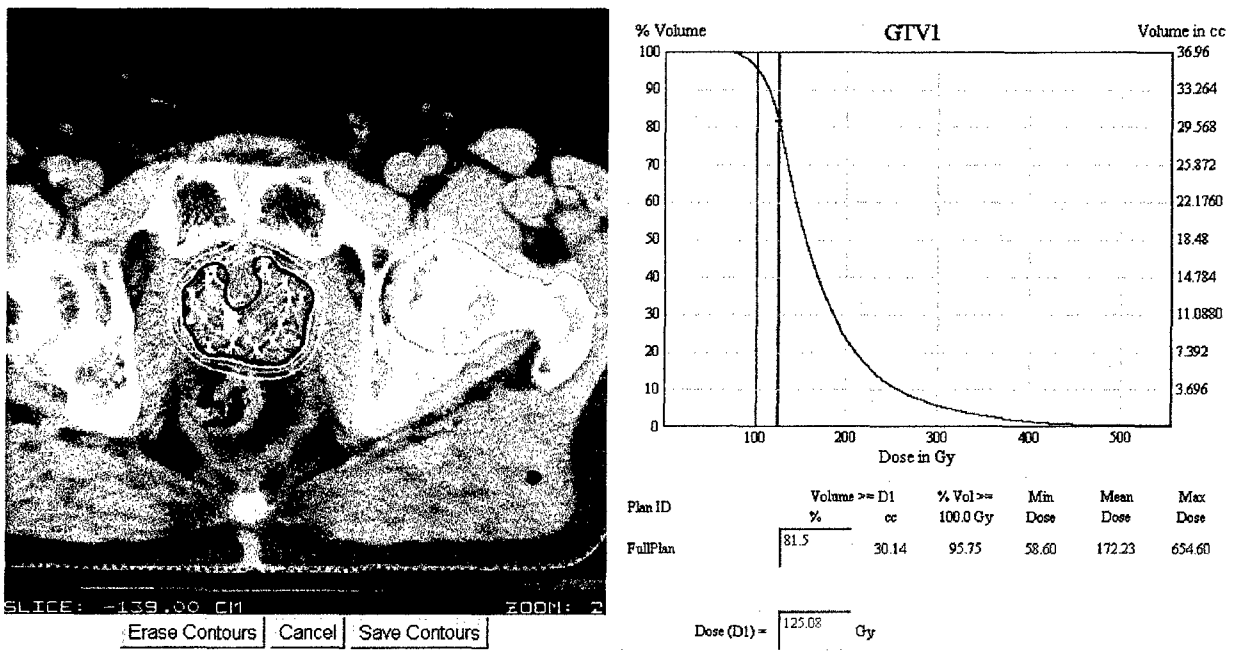

Figure 3. Java applet windows

In summary, we have successfully completed our goal to develop a program for providing centralized quality assurance reviews of treatment planning verification data submitted by participating institutions for patients receiving TIPPB as part of any future prospective, multi-institutional research trials. This review can be done either at the 3DQA Center or at another location using the remote review tools.

Task 4. Develop guidelines for the credentialing of institutions enrolled in national prostate brachytherapy trials and establish standards for the performance of TIPPB.

Proposed QA guidelines for the conduct of low-dose rate TIPPB for the purpose of performing national, multi institutional cooperative studies have been developed and posted on the 3DQA Center's website (http://3dqa.wustl.edu). A copy of the latest facility questionnaire that can be used in credentialing institutions is attached as **Appendix 2**. A copy of the latest QA Guidelines is attached as **Appendix 3**.

Task 5. Develop a dosimetric database to be used in the correlation of implant quality with efficacy of tumor eradication and morbidity of the procedure (months 3-30).

The 3DQA Center has designed and implemented a TIPPB treatment planning verification (TPV) database that can be linked with the RTOG clinical outcome database. The primary purpose of the TPV database is to support the quality assurance and data management for future RTOG and other cooperative group prostate implant protocols. In addition, a secondary purpose is to establish a national resource of readily accessible TIPPB planning data that can be linked to outcomes and used by clinical investigators for the analysis of secondary long-term clinical outcome studies and by researchers for the development and validation of new tumor control and normal tissue complication probability (TCP & NTCP) models.

To review briefly the TPV database, since most of the data attributes to be stored will be communicated using the RTOG Data Exchange format, it was used as the starting point for the data modeling effort for these data (radioactive seed isotope, model, strength, and implant locations). Several additional attributes were needed, however, to interpret submitted data. For example, the database records the number (and locations) of sources at several stages in the planning/implant/verification/QA process: (a) during treatment planning (with respect to pre-plan imaging), (b) at implantation, (c) during verification (with respect to post-implant imaging), and (d) in the 3DQA Center (based on received post-implant image data). Modifications of the current CT image data model was needed to represent image acquisition parameters for MR and US images. Additionally, the time interval between implant and the post-implant CT scan needed to be stored in the database. For trials requiring the submission of more than one volumetric image set, the database needed to represent the relationships between these image sets. The database schema diagram is shown in **Figure 4** below. New entities and relationships used to represent TIPPB data are shaded.

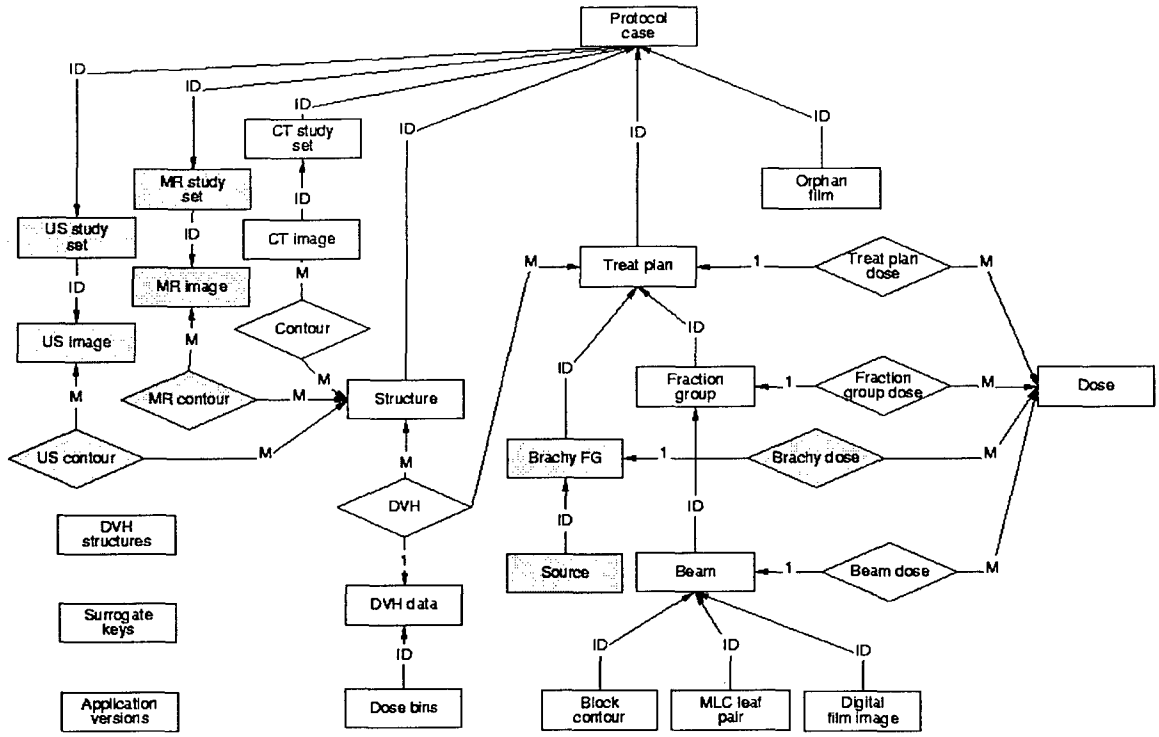

Figure 4: TIPPB modifications for RTOG 3D treatment planning verification (TPV) database schema

The current database model used by the 3DQA Center utilizes software that involves separate databases for the clinical and administrative data.[2] Thus, in addition to modifications required to store TIPPB TPV data, the administrative database used to track QA reviews of TIPPB cases was also modified to include data for QA assessment of dosimetry, organs-at-risk/target-volume definitions and dose-volume analysis permanent prostate implants. Updated user interface displays for these data are shown in Figure 5a,b,c below.

Post Plan Dosimetry Information

EDIT

Protocol: 0019 **Patient:** Test Patient **Institution:** WUSTL
Case: 9999 **Physician:** TEST **QA Cnt ID:** wustl00199999

Rx Dose	108 Gy

Registration	Jan 29, 2001
Implant Date	Feb 1, 2001
Postplan CT Date	Feb 28, 2001

Submitted:	Mar 19, 2001

	Submission Criteria	Meets Criteria	Comment
1.	**Timely Submission**	YES	
2.	**T2 Form**	YES	
3.	**Hardcopy isodose distributions**	NO	Missing
4.	**Implant Films (optional)**	YES	
5.	**Digital data (images, contours, seeds, doses, DVHs)**	YES	

	Plan ID	Seeds Implanted	Seeds Counted	Air Kerma Strength
Institution	brachy1	89	87	0.5
QA Center	postplan		88	

Reviewed by:	WRB	Mar 20, 2001

Mon Mar 26 09:52:43 CST 2001 *Form last modified Mar 24, 2001 12:45 am by walter.*

Figure 5a: TIPPB Modifications for RTOG 3D QA Database User Interface: Post Plan Dosimetry

Organs at Risk, Target Volume

EDIT

Protocol: 0019 **Patient:** Test Patient **Institution:** WUSTL
Case: 9999 **Physician:** TEST **QA Cnt ID:** wustl00199999

Rx Dose	108 Gy

Registration	Jan 29, 2001
Implant Date	Feb 1, 2001
Postplan CT Date	Feb 28, 2001

Submitted: Mar 21, 2001

	Structure	Score	Comment
1	GTV_pre	0	
2	CTV_pre	0	
3	PTV_pre	0	
4	Bladder_pre	0	
5	Rectum_pre	0	
6	ETV	1	
7	Bladder_post	1	
8	Rectum_post	2	Incomplete superior extent

Other Comments: This is a test case

Reviewed by: WRB Mar 20, 2001

Composite Target Volume Score	1	Highest score among Target Volume(s)
Composite Organs at Risk Score	2	Highest score among Organ(s) at Risk
CT Data Score	1	

QA Score Definitions 1= no contouring errors 2= minor contouring problems 3= significant deviation in contours

CT Data Score Definitions 1= according to protocol 2= not according go protocol but evaluable 3= irradiated tissue not included in scan

Mon Mar 26 09:53:51 CST 2001 *Form last modified Mar 21, 2001 2:16 pm by walter.*

Figure 5b: TIPPB Modifications for RTOG 3DQA Database User Interface: Organs At Risk, Target Volumes

Dose Volume Analysis

EDIT

Protocol: 0019 **Patient:** Test Patient **Institution:** WUSTL
Case: 9999 **Physician:** TEST **QA Cnt ID:** wustl00199999

Rx Dose	108 Gy

Registration	Jan 29, 2001
Implant Date	Feb 1, 2001
Postplan CT Date	Feb 28, 2001

X **Digital dose data compared to hard copy** **Submitted:** Mar 19, 2001

A. TARGET VOLUME ANALYSIS

Target	Volume (cc)	Percent Volume Receiving ≥ 90% Rx Dose		Percent Volume Receiving ≥ 200% Rx Dose		Mean Dose (Gy)	Conformity Index	Coverage Score
ETV	67	83	% ≥ 97.2 Gy	12	% ≥ 216 Gy	120	0.67	1

B. NORMAL STRUCTURE ANALYSIS

Normal Tissue	Volume (cc)	% Vol ≥ Ref Dose	Ref Dose (Gy)	Max Dose (Gy)	Mean Dose (Gy)
Rectum_post	57	22.3	60.0	67.8	33.2
Bladder_post	128	17.3	65.0	47.3	8.2

Reviewed by:	WRB	Mar 24, 2001

Target Volume Coverage Score: $1 : V_{R_xD} \geq 80\%$, $2 : 50\% \leq V_{R_xD} < 80\%$, $3 : V_{R_xD} < 50\%$

Mon Mar 26 09:51:44 CST 2001 *Form last modified Mar 24, 2001 12:43 am by walter.*

Figure 5c: TIPPB Modifications for RTOG 3D QA Database User Interface: Dose Volume Analysis

KEY RESEARCH ACCOMPLISHMENTS

1. An updated specification for RTOG Data Exchange (v4.00) that includes brachytherapy seed sources and ultrasound images has been completed. (**See Appendix 1**).
2. The 3DQA Center held a Data Exchange workshop at the 3DQA Center in St. Louis on September 10-11, 1999 to assist and encourage representatives of several commercial RTP system manufacturers to implement the new RTOG Data Exchange Specification.

3. The 3DQA Center has implemented RTOG Data Exchange, v4.00 (both READ and WRITE) on a CMS FOCUS RTP system that can be used for centralized dose review of TIPPB protocol cases.
4. The 3DQA Center has adapted a CMS FOCUS RTP system to serve as a QA review station for TIPPB protocol treatment plans. Dose calculation and isodose display for TIPPB plan review has been tested and is functional. (Isodose can be displayed on CT images and on 3D structures for patient anatomy and target volumes; DVHs can be calculated and displayed).
5. A Facility Questionnaire and QA guidelines for the conduct of TIPPB protocols for the purpose of performing national, multi institutional cooperative studies have been developed. **(See Appendices 2 and 3)**.
6. A database to house TIPPB TPV data has been developed that can link with the outcomes database of RTOG in order to correlate implant quality with efficacy of tumor eradication and morbidity of the procedure.

REPORTABLE OUTCOMES

1. Publications

- Matthews JW, Harms WB, Bosch WR, Purdy JA, "Digital data exchange for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy", published in Proceedings of the XIIIth International Conference on The Use of Computers in Radiation Therapy, May 22-25, 2000, Heidelberg, Germany, edited by W. Schlegel and T. Bortfeld, 116-118, 2000. **(See Appendix 4)**
- Bosch WR, Harms WB, Matthews JW, Purdy JA, "Database infrastructure for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy", published in Proceedings of the XIIIth International Conference on The Use of Computers in Radiation Therapy, May 22-25, 2000, Heidelberg, Germany, edited by W. Schlegel and T. Bortfeld, 483-485, 2000. **(See Appendix 5)**

2. Meetings

a. 3DQA Center Meeting – October 5, 1998

A meeting of the RTOG/DOD Prostate Cancer Brachytherapy Research Group was held in St. Louis, Missouri on October 5, 1998. Attendees included Jim Purdy, Ph.D. (Chair); William Bice, Ph.D.; Walter Bosch, D.Sc.; William Harms, B.S., John Matthews, D.Sc.; William McLaughlin, M.D.; Jeff Michalski, M.D.; Sasa Mutic, M.S.; Bradley Prestige, M.D.; Peter Roberson, Ph.D.; Jeffrey Williamson, Ph.D. The following was extracted from the 3DQA Center's meeting minutes.

"Specifically, the following assignments were made: (a) Drs. Prestige and Bice were to develop a first draft of TIPPB QA Guidelines following the format of the RTOG 98-03 external beam QA guidelines available on the QA Center's Web Site. (b) Drs.

McLaughlin and Roberson were to develop a first draft of a TIPPB Questionnaire following the format of the RTOG external beam questionnaire available on the QA Center's Web Site. (c) Mr. Harms was to develop a first draft of the new digital data exchange specification. (d) Dr. Bosch will begin extending the data model to represent brachytherapy sources and the other imaging modalities pertinent to TIPPB. (e) Dr. Matthews will begin implementing software to allow TIPPB dose calculation and display on a 3DQA review system."

b. RTOG Meetings

January 17, 1999

The 3D QA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Atlanta, Georgia on January 17, 1999. 3D QA Center attendees were J. Purdy and J. Michalski.

July 17, 1999

The 3D QA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Philadelphia, PA on July 17, 1999. 3D QA Center attendees were W. Harms and J. Michalski.

January 20-23, 2000

The 3DQA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Philadelphia, Pennsylvania. 3DQA Center attendees were J. Purdy and J. Michalski. The following was extracted from the 3DQA Center's meeting report submitted to RTOG.

"Substantial progress has been made in establishing a methodology for electronic data exchange of prostate brachytherapy treatment planning verification data between institutions participating in a future prostate brachytherapy protocol and the 3DQA Center. In addition, a proposed credentialing process and QA guidelines has been posted on the 3DQA Center's website. Work is in progress in modifying a CMS FOCUS 3DRTP system to serve as a 3DQA review station of clinical and dosimetric data for patients entered on RTOG prostate brachytherapy protocols."

The following summarizes the work accomplished thus far.

- A final specification for RTOG Data Exchange (V4.00) that includes brachytherapy seed sources, MRI and ultrasound images has been completed.
- READ for all objects described in the RTOG Data Exchange V4.00 into FOCUS data structures has been completed. This includes permanent prostate seed implants.
- Work has been completed in implementing a WRITE of RTOG Data Exchange for a prostate brachytherapy treatment plan data set per the final specification.

- FOCUS QA review station isodose calculation and display for TIPPB plan review has been tested and is functional. (Isodose can be displayed on CT images and on 3D structures for patient anatomy and target volumes).
- FOCUS QA review station DVH calculation and display for TIPPB plan review has been tested and is functional.
- Proposed QA guidelines for the conduct of low-dose rate TIPPB for the purpose of performing national, multi institutional cooperative studies have been developed.
- The 3DQA Center held a Data Exchange Workshop in St. Louis on September 10-11, 1999. Representatives of several commercial RTP system manufacturers attended the workshop.

June 23-25, 2000

The 3DQA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Montreal, Canada. 3DQA Center attendees were W. Harms and J. Michalski. The following was extracted from the 3DQA Center's meeting report submitted to RTOG.

"We have completed the establishment of the methodology for electronic data exchange of prostate brachytherapy treatment planning verification data between institutions participating in a future prostate brachytherapy protocol and the 3DQA Center. The 3DQA Center has completed all work required to review submitted TIPPB data sets using the expanded RTOG Data Exchange (V 4.00) Specification. One RTP vendor (CMS) has completed the implementation of the data exchange for TIPPB as evidenced by a user submitting a data set for review. Varian Medical Systems (MMS) has verbally committed to completing the implementation by October 2000.

The proposed credentialing process and QA guidelines has been posted on the 3DQA Center's website for comment, though little comment has been received thus far. The following summarizes incremental work since the January 2000 report:

- READ for all objects described in the RTOG Data Exchange V4.00 into FOCUS data structures has been updated to FOCUS version 2.6.0. This version of FOCUS includes tools for automatic seed localization which may be used as a QA review of submitted data"

Feb 16-18, 2001

The 3DQA Center provided an update to the RTOG membership regarding the RTOG/DOD Prostate Cancer Brachytherapy Research Project at the RTOG semi-annual meeting held in Tampa, FL. 3DQA Center attendees were W. Harms and J. Michalski. Meetings were held with representatives of the RPC and the QA physicist for the RTOG P-0019 (TIPPB) protocol to review and coordinate the 3DQA Center's activities in digital submission with the traditional hardcopy approach used in the past. The remote review tools developed by the 3DQA Center were demonstrated and their use in credentialing and QA review activities were determined. Joint credentialing and QA review activities for those participants utilizing the one compliant treatment

planning system (CMS FOCUS) were discussed and coordination tasks were identified for implementation.

c. DICOM Working Group 18 Meetings

November 16, 1999

Walter Bosch represented the 3DQA Center at a meeting of DICOM Working Group 18 (WG18), held on November 16, 1999 in Chevy Chase, Maryland. WG18 was convened to discuss the use and extension of the DICOM standard for the exchange of data in clinical trials and for regulatory submissions. Co-conveners of WG18 who were present include David Clunie (Quintiles Intelligent Imaging), Ed Staab (NCI), and Curt Langlotz (ACR). Organizations supporting co-operative clinical trials were represented by Peter Balter (RPC) and Rex Welsh (ACR). Academic physicians as well as representatives of the FDA and several medical imaging and bio-informatics companies were also present.

David Clunie reviewed several issues that had been raised in earlier meetings of the WG. These include the following:

- Data security and confidentiality;
- The need for identification above the level of patient (i.e., protocol) in clinical trials;
- Associated links to related entities in a submission;
- Data transport, i.e., TCP/IP and physical media (no support for FTP or HTTP in DICOM);
- The use of coded terminology, de-referenced through dictionaries (Master List of Codes, DICOM Part 16, to be released soon), several dictionaries are being developed. Including SNOMED, UMLS, and DICOM Terminology Mapping Resource (DTMS);
- Other standards organizations pursuing overlapping data standards, including CDISC, ISO, HL7; and
- DICOM structured reporting – hierarchical structure, which refers to DICOM, objects and describes their meaning for a given context.

Curt Langlotz presented a review of the Cancer Information Infrastructure (CII) and Common Data Elements (CDE) initiatives of the NIH and Oracle Corporation. CDE is an effort to develop consistent data collection methods for clinical trials by defining "building blocks" for representing clinical information. Information concerning the CDE initiative was offered via the web at http://cii.nci.nih.gov/cde.

Representatives of organizations supporting clinical trials gave several presentations.

- Peter Balter presented an overview of the activities of the RPC. Requirements for dosimetric quality assurance in multi-institutional clinical trials were discussed.

- Walter Bosch presented the history, responsibilities, and operations of the 3DQA Center at Washington University. The nature of treatment planning and verification data submitted for protocols, the mechanism used for data exchange, and steps in

the QA process were described. Currently supported protocols and developmental activities of the 3DQA were outlined.

- Rex Welsh reported on activities of ACRIN (ACR Information Network) in support of radiological trials. He described the experience of the ACR with a 14-institution MRI breast trial and indicated that 8 of the participants showed resistance or inability to submit images as DICOM. He described a Windows application being developed which includes a simple image viewer and means for scrubbing patient identifiers and adding protocol information prior to submission. Systems are to be equipped with dual network interfaces for receiving data from a hospital network and submission via the Internet (using SSL).

Several issues related to data security were discussed. Supplement 31 to the DICOM standard addresses both confidentiality and authenticity of data transfers. By using the Secure Sockets Layer (SSL) standard with the TCP/IP network protocol, the existing DICOM data transport mechanism can be used securely. Issues of anonymization were raised and differences in the requirements between clinical trials and regulatory data submissions were noted.

It was the consensus of those present that the scope of WG18 should include the following:

- Things which should be added to the DICOM standard to support clinical trials and regulatory submissions;
- Structured Reporting for linkage of non-image information; and
- Formal liaison with NCI on the development of Common Data Elements for clinical trials.

February 1, 2000

Walter Bosch represented the 3DQA Center at a meeting of DICOM Working Group 18 (WG18), held on February 1, 2000 at ACR Headquarters in Philadelphia, Pennsylvania. At this meeting, Andrew Kraus (Biocor) presented a list of DICOM tags that are used in images to be submitted in clinical trials. Issues raised in this discussion include:

- The desirability of a "minimalist approach" for identifying images using a Protocol ID, Protocol Sponsor, and Protocol Case Number;
- The need to maintain an audit trail for images submitted in regulatory trials;
- The need to remove/encrypt patient identifiers for patient confidentiality and for blinded reads and whether such changes require generating new DICOM unique identifiers (UIDs) in information objects; and
- The importance of maintaining compatibility with existing workstations and software in any proposed changes in the use of DICOM tags.

March 28, 2000

Walter Bosch represented the 3DQA Center at a meeting of DICOM Working Group 18 (WG18), held on March 28, 2000 in Rockville, Maryland. At this meeting, Brad

Erickson (Mayo) presented a model for workflow in clinical trials. A brief discussion followed on patient identification tags in the existing DICOM standard and on whether to re-use these attributes for clinical trials. Representatives of Adobe Systems made a presentation about submissions in PDF format. The possibility of embedding DICOM images in PDF documents was discussed. The use of removable media for image submissions was also addressed. Finally, David Clunie discussed the use of DICOM structured reports for providing a context in which to report images for submissions.

July 11, 2000

Walter Bosch represented the 3DQA Center at a meeting of DICOM Working Group 18 (WG18), held on July 11, 2000 at FDA, CBER in Rockville, Maryland. Much of this meeting was devoted to a presentation by Michael Fauntleroy (FDA, CBER) on the history, direction, and requirements of the FDA in its use of electronic images. Dean Bidgood (DICOM) presented an extended description of structured reporting as a DICOM-integrated, template-driven means for submission of clinical report data.

This meeting ended with a focus on the immediate need to define a minimal set of DICOM tags for clinical trials. Two classes of tags are needed: (1) those used to identify image data and (2) those which supply data about images (e.g., film scanner pixel spacing) which are not currently supported by the DICOM standard. Further work is needed to determine whether to re-use existing tags or to propose a Clinical Trials Identification Module as a change to the DICOM standard.

CONCLUSIONS

A methodology for electronic data exchange of TIPPB treatment planning verification data between institutions participating in a future TIPPB protocol and the 3DQA Center has been established. In addition, the 3DQA Center has developed a credentialing process and QA guidelines. A 3DRTP system has been adapted to serve as a 3DQA review station of clinical and dosimetric data for patients entered on RTOG and other cooperative group TIPPB protocols. Remote review tools that allow centralized QA and dose evaluation have been developed. A national database for the TIPPB treatment planning data that can be linked with clinical outcome data has been developed.

REFERENCES

1. Harms, W.B., Bosch, W.R. and Purdy, J.A.: An Interim Digital Data Exchange Standard for Multi-Institutional 3D Conformal Radiation Therapy Trials. Leavitt, D.D. and Starkschall, G (eds). XII ICCR, Salt Lake City, Utah, May 27-30, 1997, Medical Physics Publishing, Madison, WI, pp. 465-468, 1997.

2. Bosch, W.R., Lakanen, T.L., Kahn, M.G., Harms, W.B. and Purdy, J.A.: An Image/Clinical Database for Multi-Institutional Clinical Trials in 3D Conformal Radiation Therapy. Leavitt, D.D. and Starkschall, G (eds). XII ICCR, Salt Lake City, Utah, May 27-30, 1997, Medical Physics Publishing, Madison, WI, pp. 455-457, 1997.

APPENDICES

Appendix 1: Specification for RTOG Data Exchange (v4.00) that includes brachytherapy seed sources and ultrasound images.

Appendix 2: Credentialing document *"Facility Questionnaire"* for the conduct of national, multi-institutional cooperative studies of low-dose rate TIPPB.

Appendix 3: QA guidelines for the conduct of national, multi- institutional cooperative studies of low-dose rate TIPPB.

Appendix 4: Copy of manuscript: Matthews JW, Harms WB, Bosch WR, Purdy JA, *Digital data exchange for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy*, published in Proceedings of the XIIIth International Conference on The Use of Computers in Radiation Therapy, May 22-25, 2000, Heidelberg, Germany, edited by W. Schlegel and T. Bortfeld, 116-118, 2000.

Appendix 5: Copy of manuscript: Bosch WR, Harms WB, Matthews JW, Purdy JA, *Database infrastructure for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy*, published in Proceedings of the XIIIth International Conference on The Use of Computers in Radiation Therapy, May 22-25, 2000, Heidelberg, Germany, edited by W. Schlegel and T. Bortfeld, 483-485, 2000.

Appendix 6: List of personnel who contributed to this effort.

Specifications for Tape/Network Format for Exchange of Treatment Planning Information

RTOG 3D QA Center

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Version 4.00
12 October 1999

Please send suggestions and comments to:

Bill Harms

Based on **AAPM Report #10** and as used and modified by the **NCI Particle Intercomparison Contract,** the **NCI High Energy Photon External Beam Treatment Planning Contract,** the **NCI Electron External Beam Treatment Planning Contract,** and the **RTOG 3D QA Center.**

CONTENTS

11. DOSE-VOLUME HISTOGRAMS

12. SEED GEOMETRY

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0. PREFACE

This Tape/Network Format Specification, while initially based on AAPM Report #10, has been significantly altered to allow more information to be included in the data transfer. It was originally modified by the NCI Particle Intercomparison contract, then used in that form by the NCI High Energy Photon External Beam contract. The document was modified further for the NCI Electron External Beam contract. The modification in this version reflect further trimming of unused image types with the intent to add more image types that directly impact on exchange of treatment planning and treatment verification.

A significant modification was made with version 3.00 as it included several heretofore unsupported data image types. These new image types include beam geometries, digital film images, and dose-volume histograms. Additionally, several changes were made to dose distributions to remove ambiguities involving the submission of other than absolute dose.

With Version 3.10, an apparently ambiguous keyword was removed and more clarifying comments and examples were added. An additional keyword was added for beam geometry to identify the algorithm used for calculating doses from the beam. All of these additional keyword additions, or deletions, are optional in nature to maintain compatibility with Version 3.00. To simplify network exchange of these data files, the requirement for "buffered" data blocks is removed as an option (to be agreed upon by sending and receiving site). As many institutions are originally writing their files in this format and then post processing them to "block" them, this should come as a welcome change. This "unbuffered" submission is only available for electronic exchange of the data and the use of buffers will still be required for any tape media data exchanges.

Version 3.20 added an additional keyword for digital film images "Collimator Angle" (primarily DRR's without portal marking in the image) and one for beam geometry "Head In/Out". These were to clear up ambiguities and oversights in the previous version. DRR's are computed by two primary geometric methods, one removes the collimator angle from the transformation matrix used for computing the DRR and the other always has the edges of the image parallel to the collimators (the collimator angle is left in the transformation matrix). The "Collimator Angle" keyword identifies the method being used and is optional if the DRR edges are parallel to the unrotated collimator. The "Head In/Out" was added to resolve potential ambiguity in the couch angle wherein a 180 degree offset was added to the couch angle to signify a foot in treatment. If that patient is being treated with their feet to the gantry (prior to any couch rotation),

this keyword must be used, otherwise, head in is assumed.

Changes were made in the document for Version 3.21 which mostly amounted to additional explanation of keywords and data inclusion. There were several keywords for Beam Geometry, Digital Films and Dose-Volume Histograms which were moved from the *Required Keywords* to *Optional Keywords.* This was primarily to simplify the directories by removing requirement on any data which was not necessary to interpreting the data provided in the file set.

As more institutions begin to participate in studies requiring the use of this data exchange specification, it is inevitable that further refinement and ambiguity resolution will have to be done. This is a living document and will be subject to many revisions over the next year or two until it is replaced with more robust and universal communication mechanisms such as DICOM 3.0.

Version 4.00 was created to provide for ultrasound guided permanent prostate seed implants. Additional items were added in support of Peregrine and other projects. Those which were added which are not supported by the 3D QA Center are identified as such in the text.

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1. REVISION HISTORY

Version	Date	Description
1.0	4/22/82	Preliminary draft. (Michael Goitein)
1.1	8/28/82	Substantially modified. All images in ACSII except CT scans
1.2	10/21/83	Intermediate update - never distributed.
2.1	12/27/83	Working version. Document clarified and reorganized. New requirement that CT images be contiguous on tape in order of increasing z-coordinate Explicit description of how null characters are to be handled. (nulls not included in byte counts).
2.2	4/08/85	Revisions made in conjunction with Robert F. Curley: Add dose examples Add text describing in words the data files for structures and doses. Require "....." must not contain CR/LF Require all CT scans to be square. Add a number of clarifying comments.
2.3	09/22/89	Remove annotations and code examples for ECWG report (Harms)
2.4	07/08/92	Remove additional information on annotations, cleaned up the grammar, added variances relating to the amount of data on a tape (multiple patients, buffer size, and tape density), added new "image" types of MRI, Beam Geometry, and digital film images (i.e. DRR, on-line images). (Harms)
2.5	06/29/93	Fixed errors in document pertaining to keywords "Maximum # of scans" to "Maximum # scans" and "Scan type" to "Scanner type" (Harms)
2.51	07/09/93	Clean up language and add "Writer" as a Directory Header entry (as it was inadvertantly left out from the original format)
3.00	1/10/94	Added Beam Geometry, Digital Film, DVH's and fractionation information. Included moving appendices into appropriate chapters and modified dose distributions to allow for fractionation information and to clarify dose units. (Prostate Working Group, Bill Harms, Jonathan Jacky, Jeff Lewis and James Balter).

3.10	6/10/94	Added more explanation and cleaned up some partial omissions. Allowed unblocked data (for network transmission) if receiving site is agreeable and removed "INTERCOMPARISON STANDARD #" as an ambiguous keyword. Removed AAPM Report 10 as the standard to judge discrepancies in the exchange format.
3.20	12/28/94	Added "Head In/Out" keyword to beam geometry and "Collimator Angle" keyword to digital film images for DRR's.
3.21	3/8/95	Added clarifying discussion to many keywords and moved unnecessary keywords from Required, to Optional.
3.22	4/17/97	Corrected error in MLC example.
3.30	7/25/97	Optional extensions added to Beam Geometry and Dose for support of Peregrine communications and more succinct and explicit treatment plan information exchange. Some additional clarification text was incorporated based on comments by George Starckschall. The primary additions to Beam Geometry are explicit compensating filter descriptions, a Machine ID keyword (in addition to energy and modality), and Beam Weight and Weight Units to allow for machine settings to be specified. The optional additions to Dose allows for binary dose files (two's complement integer with a scale factor) to reduce the size of dose image files. Following are links to the modified text for ease of locating. • ASCII restrictions • Date Format for Y2K • Coordinate System Clarification • Asymmetric Jaw Clarification • Compensating Filters • Additional Beam Geometry (Optional) Keywords • Digital Film Modification (Text) • Digital Film Modification (Keywords) • Dose Modification for Binary Data (Text) • Binary Dose Sample Description • Additional Dose Keywords (Optional) for Binary Data (Keywords) • DVH Data Format Clarification
4.00 Draft	03/22/1999	Changes made for Version 4.0 of this Exchange Specification were motivated by the need to add prostate seed brachytherapy treatment planning to the information supported by this exchange. In order to make use of the appropriate imaging modalities which are used for permanent prostate seed implants, MRI and ultrasound (US) were added to the CT Scans chapter and an additional file type was defined for Seed Plan specification. One previously documented feature has been removed. While the Specification "officially" supported multiple patient data sets in a single file set, no commercial or University systems being used for patients enrolled in multi-institutional trials made use of this feature, therefore, to simplify the implementation of reading and writing software, this feature has been removed. This allows the Case keyword to be used as desired by the writing facility. A suggestion would be to use the actual patient registration number as the case number, but in order to maintain backward compatibility with writing software, this is not going to become a requirement at this time.

One additional change was to incorporate beam aperture definitions through the use of a transmission table in addition to closed block and portal contours. This addition was made to facilitate the exchange of this information with the Peregrine system and is not currently used, or supported by the RTOG 3D QA Center for protocol patient data submissions.

Following are links to the modified text for ease of locating. Also, note that all added text is in this same color purple text to aid the reader. Incorrect compensating filter examples were also corrected.

- Case number modification
- Patient Coordinate system clarification for CT, MRI, and Ultrasound image sets
- MRI and Ultrasound image files
- Warning about MLC Specification
- Transmission Map Information (in lieu of block or MLC coordinate specification)
- Compensating filter example data correction
- Seed Geometry

4.00 10/12/1999 Changes made from the Draft Version 4.0 of this Exchange Specification were the result of the implementation workshop in September, 1999 where most of the brachytherapy developers provided input into items requiring correction or adjustment. These changes generally added clarification to the document, but in some cases, removed some of the draft items or added items which would not result in legacy code failing.

The optional keyword for Seed Geometry, "Registered" has been removed and replaced with the implicit assumption that if any CT/MR/US images are included in the same file set as one (or more) Seed Geometry files, the seeds are registered with the included images.

Following are links to the modified text for ease of locating. Also, note that all added text is in this same color purple text to aid the reader.

- Seed Geometry file set order recommendations
- CT/MR/US coordinate system clarification for offsets
- Secondary capture as source of CT/MR/US images
- Several, formerly required, maximum counts made optional for STRUCTURES
- Dose # and Dose Type made optional
- Plan ID of Origin added to DOSE to connect seed geometry and dose distribution
- Seed-Image Registration Requirements

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2. INTRODUCTION

The format proposed follows the recommendations of the AAPM for digital image transfer, published as AAPM report no. 10, "A Standard Format for Digital Image Exchange" (obtainable from: AAPM, One Physics Ellipse, College Park, MD 20740). The description in this document assumes the reader's familiarity with AAPM Report #10. The tape format described in this document is intended to comply with all aspects of AAPM Report #10. Some aspects of that report are reiterated here as a help to the reader. However, in the event of a real or apparent discrepancy, AAPM Report #10 shall give way to this document. This document extends the scope of AAPM report #10 by including data structures other than CT scans or comparable images.

Seven types of files (termed images in the AAPM standard) are supported (in addition to the Directory): Comments; CT scans; Structures (target volumes, external contours, normal critical structures, etc.); Beam Geometry's; Dose distributions; Digital Film Images and Dose-Volume Histograms. No more than one case can be transmitted on one tape (or network file data set). The data shall be placed on tape in the following order, case by case.

Comments	case 1
Scans (CT, MRI, US)	case 1
Structures	case 1
Orphan Digital Film Images	case 1
Beam Geometry's	case 1 (plan 1)
Digital Film Images	case 1 (plan 1)
Doses	case 1 (plan 1)
Dose-Volume Hist.	case 1 (plan 1)
Beam Geometry's	case 1 (plan 2)
Digital Film Images	case 1 (plan 2)
Doses	case 1 (plan 2)
Dose-Volume Hist.	case 1 (plan 2)
.....	.....
Beam Geometry's	case 1 (plan n)
Digital Film Images	case 1 (plan n)
Doses	case 1 (plan n)
Dose-Volume Hist.	case 1 (plan n)
etc.	

Not all data is required in this order. For instance, if beam geometry's and digital film images are no submitted with the corresponding doses and dose-volume histograms, the non-existent data will just be left out of the data to be transmitted. An example of such an order would be:

Scans	case 1
Structures	case 1
Doses	case 1 (plan 1)
Dose-Volume Hist.	case 1 (plan 1)
Doses	case 1 (plan 2)
Dose-Volume Hist.	case 1 (plan 2)
.....	.....
Doses	case 1 (plan n)
Dose-Volume Hist.	case 1 (plan n)
etc.	

Seed Geometry and Beam Geometry are mutually exclusive and both may not be contained in a single file set. In the case of a file set containing Seed Geometry, the following demonstrates the order of the files:

Scans (CT/MR/US)	case 1
Structures	case 1
Seed Geometry (one set of seeds)	case 1 (plan 1)
Doses	case 1 (plan 1)
Dose-Volume Histograms	case 1 (plan 1)
Seed Geometry (second set of seeds in same implant)	case 1 (plan 2)
Doses	case 1 (plan 2)
Dose-Volume Histograms	case 1 (plan 2)
etc.	

If multiple Seed Geometry files are contained within a given file set, it is assumed that they represent different activity and/or model seeds used in the same implant.

Examples of a directory header and some (non-binary) images are included in the following chapters.

There are two distinct coordinate systems used by this Specification. One is for patient data which is defined in Chapter 6. The other is for the beam aperture specification which is oriented in a "beam's-eye view" manner in which aperture coordinates are 2D coordinates with a constant third coordinate relative to distance from beam source and is defined in Chapter 8.

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3. DISTRIBUTION MEDIA CONVENTIONS

3.1 TAPE EXCHANGE

A 9-track tape with a density of 1600 bpi shall be the default medium used for data exchange. However, if the site to receive the tape agrees to higher density, and/or a different type of physical tape, it shall be allowed. Tapes shall be UNLABELED to facilitate intercommunication between different manufacturer's computers. Multi-volume tapes should not be used unless necessary to transmit a single case. For tapes which can have their densities changed, the tape must be clearly labeled and the used density agreed to by

the receiving institution.

All data on the tape shall be written in fixed length buffers. The default buffer size is 2048 bytes, but if the receiving site agrees to a different size buffer, it is allowed and should be clearly marked on the tape. As many buffers are written as are required to transmit the data, unused bytes (such as the unused remaining bytes of the last buffer of an image) shall be filled with NULL characters. No text strings should be broken across buffer boundaries. If an entire string will not fit into the current buffer, the end of the buffer should be NULL'ed out and the string put into the next buffer.

Single end-of-file marks separate the directory file from the first "image" file and succeeding image files from one another. Two end-of-file marks in succession terminate the tape. On media other than 9-track tape, these separation requirements may not be valid and adjustments may need to be made.

3.2 NETWORK EXCHANGE

If both the sending and receiving site have network access to one another, this data may be sent as individual files across the network. The means of such transfer are left for the sending and receiving institutions to work out among themselves. Recent experience has shown that anonymous ftp, in binary mode, is a practical method of such data transfer where the files' names have a numeric identifier in their names so that the order is obvious for processing (the author's preference is "aapm0000", "aapm0001", etc.). However, anonymous ftp might present patient record confidentiality problems. This could require the submitting institution(s) to have distinct login accounts on the receiving machine(s) which segregate them from other institutions data submissions and shield the data they submit from others.

For network exchange of data, if the receiving site agrees, the data may be sent in files of a single buffer the size of the data file. The fixed length buffer requirement may be disregarded in this case. However, for media exchange of data, in the interest of preventing any possible hardware/software incompatibility, fixed buffers are still REQUIRED. This is a change for Version 3.10.

3.3 DATA STORAGE

Two types of data can be stored on tape: BINARY data, for CT scans and digital film images; and ASCII character strings (terminated with <CR/LF>) for everything else (including the directory file). The two types of data may **NOT** be mixed within any given file.

3.3.1 BINARY Data

For each binary datum which occupies 2 bytes of the buffer, in compliance with the AAPM standard, the most significant byte is required to be first. Thus VMS, and similar byte order, machines will need to byte-swap both when writing and when reading a tape, for instance. For the unsigned byte data, the order is obvious.

3.3.2 ASCII Data

ASCII data may appear in one of two contexts: In the directory header where the data is always in the form of keyword/value pairs (see below); and in images (such as structure definitions or dose distributions) - where the format depends on the data type, but is generally largely a sequence of numeric fields (i.e. ASCII strings defining real or integer numbers as appropriate). In either context the following rules apply.

Each entry of ASCII text may be from 1 to 80 bytes in length (excluding null bytes which are ignored) and

must be terminated by a carriage-return/line-feed (CR/LF) sequence (not included in the 80 byte limit). Embedded spaces, tabs and null characters should not be included within numeric fields (but may precede or follow them) and elsewhere (as in keywords) they are to be ignored. Blank lines (CR/LF/CR/LF) are to be ignored in the parsing of these files. To permit comments in numeric fields (in order to make a printed file more interpretable), any text enclosed in double quotation marks (") is to be ignored. Text between quotation marks may not include a CR/LF string.

When specifying numeric data, a comma/space (comma followed by a space) sequence is an acceptable field delimiter as well as the CR/LF sequence. *ADD1: Note, however, that no text line may end with a comma/space/CR/LF sequence as the comma/space implies further meaningful text in the line.* No text string may bridge multiple buffers, if buffered exchange is selected or required. While the specification technically allows it, it generally presents implementation problems and shall not be supported.

3.3.3 NULL Characters

Unused elements of the last buffer of a binary image (if any) are ignored. They may be filled with zeros.

Null characters may occur anywhere within ASCII Text (except in the middle of a numeric field) and are tc be ignored. Null characters are not counted in any per line byte count limit. Generally, it is expected that null characters will be used to pad out at least the final buffer of an image, and should be used to pad out the final elements of intermediate buffers to avoid having text cross buffer boundaries. Only binary data may cross buffer boundaries.

---

4. DIRECTORY

The first file is a directory file, written entirely in ASCII characters. The directory consists entirely of Keyword/Value pairs - as described in the AAPM standard specification and in this document. At present no files or "images" other than the directory contain keyword/value sequences. Keywords and values are case and space insensitive. For instance:

```
Somewhat longer keyword :=
```

is equivalent to:

```
SOMEWHAT       LONGER          KeywoRd :=.
```

The first entries in the directory pertain to the entire tape and constitute the "directory header". Keywords used in the directory header are given in the following section. The directory header is followed by sequences of keywords which relate to individual images. By convention the first such keyword shall be "Image #", and all keywords relating to an image should follow that "Image #" specification and should precede the next "Image #" occurrence.

Note that "Image #" is a misnomer introduced by the AAPM format for tape exchange. It really just identified the position of the file on the tape. However, it does reference the sequence number of the associated file for network transferred data files. The first file is the directory (perhaps best thought of as file number 0), and subsequent files are termed "images" and assigned consecutive numbers starting from 1. In the present case, these "images" may in fact be any one of: Comments, CT scans, Structures, Beam Geometry's, Digital Film Images, Dose Distributions and DVH's.

Spaces, tabs and null characters are to be ignored in keywords. Alphabetic characters may be in upper or lower case and, in interpreting strings of characters as keywords (program implementation), all lower case characters may be replaced by their upper (or lower) case equivalents. In order to remove a potential source of confusion, the character strings "number" and "#" in keywords are to be everywhere considered interchangeable and **MUST** have numeric values.

In conformity with the AAPM standard, directory entries are made in the format:

```
Keyword := value
```

In this context only one "value" can follow the "=". Thus a mixed expression such as "size : = 1.5 cm" is illegal. There is to be no character (null, space, or otherwise) between the ":" and the "=".

In order to make tape listings somewhat more readable, it is permissible (indeed encouraged) to include tabs to make successive entries line up, as:

```
Keyword                  :=    STRUCTURES
Somewhat longer keyword  :=    18
Next keyword             :=    10.65
```

The AAPM *tape* format virtually mandates a two-pass approach - that is, two passes have to be made through the data to be transferred: the first in order to build up and write out the entire directory; the second in order to write out the underlying data to tape. This may be avoided if the files are built on disk first and the physical writing of the tape subsequent to the completion of all data files and the directory being written to disk. Network transfer will involve building the files on disk with the directory file being written to disk last (even though it has a smaller file number, i.e. 0).

4.1 Keywords for the Directory Header

Required Keywords

```
Tape standard # :=    4.00  (version # of this standard from title page)
Institution     :=    Name of submitting institution
Date created    :=    Date tape written in AAPM format (dd, mm, yyyy)
Writer          :=    Name of person responsible for writing tape
```

These entries **must** be the first entries in the directory.

Optional Keywords

```
Intercomparison standard # :=   version # of this standard from title
                                page (4.00) this keyword is maintained
                                only for compatibility and its' use is
                                not recommended
```

Format of data in the image:

No image is associated with the directory header.

4.2 Sample Entries in the Directory Header

```
Tape standard # :=    4.00
Institution     :=    MIR
Date created    :=    22, 03, 1999
```

```
Writer          :=    Bill Harms
```

The date format used for all dates specified in a directory for a data exchange file set must be in the format DD, MM, YY[YY], where DD is the day of the month (one or two digits are allowed), MM is the month of the year (one or two digits are allowed and 1-January, 2-February, etc.), and YY is the last two digits of the year with an implied 1900 added to it. *Four digits may be used for the year for Y2K compliance (and **must be used after 12/31/1999**).*

Note that a date may be legal in format, but due to the time of any given month in which the date is generated, it may be incorrect. For instance, if a file set is generated on the 9th of February 1995, the date string should be `9, 2, 95`. However, `2, 9, 1995` is a legitimately formatted date, but is incorrect. This should be carefully reviewed during implementation as it is a frequent mistake.

There are four keywords which are common to all image files (regardless of the image file content). These keywords must be used for all image files and must be in the order specified for the proper implementation of the data exchange format.

Required Keywords

```
Image #       :=    actual image (file) number
Image type    :=    COMMENT, CT SCAN, MRI, ULTRASOUND, STRUCTURE,
                    BEAM GEOMETRY, DIGITAL FILM, DOSE,
                    SEED GEOMETRY, or DOSE VOLUME HISTOGRAM
Case #        :=    1 for first case(optionally protocol case #)
Patient name  :=    patient identifier
```

The Image # is the ordinal number of the data file being referenced. In the case of tape being used as the transport medium, this number is the order in which the files are found on the tape in which the first file is the directory file and is considered file number zero (0). Therefore the first data file would be 1, the second, 2, etc. In the case of a network medium of exchange, these number must be explicitly represented in the file names attached to the individual files. Again, the directory file is file zero (0).

The Image type is used to identify the data contained in the associated image file. With the exception of CT SCAN, MRI, ULTRASOUND, DIGITAL FILM and binary dose files (optional) all data files are in ASCII format.

The Case # identifies the ordinal value of a patient in an exchange file set. Since multiple patient data sets are eliminated from this specification, this number may have any integral value and one suggestion would be to make it represent the case number assigned by the cooperative group for the protocol the patient is enrolled in.

The Patient name is not required to be the patient's real name. However, it should have the same value for all image files for the same patient in the exchange file set. For RTOG 3D QA Center purposes, it should be the patient's name or some other identifier which the submitting institution can use to identify the data set in question should the 3D QA Center have questions about the case..

```
Image #       :=    1
Image type    :=    COMMENT, CT SCAN, STRUCTURE, BEAM GEOMETRY,
                    DIGITAL FILM, DOSE, or DOSE VOLUME HISTOGRAM
Case #        :=    1
Patient name  :=    John Q. Public
```

---

5. COMMENT

This feature provides the capability of transmitting substantial textual material such as a clinical case history. The format of the data is as a sequence of ASCII text strings, each of no more than 80 characters, of arbitrary length. Although the comment text can be entered in any way desired, the most likely mechanism would be to provide a utility to read a file created with the computer's text editor and copy it into the comment "image" after adding the appropriate <cr/lf> line terminators and buffering. An example in 5.3 illustrates this.

5.1 Keywords for Comments Used in Directory

Required Keywords

```
Image #              :=    actual image (file) number (see 4.4)
Image type           :=    COMMENT
Case #               :=    1 for first case, 2 for second case, etc.
Patient name         :=    patient identifier
```

Optional Keywords

```
Writer               :=    person responsible for data
Date written         :=    date file written (DD, MM, YYYY)
Unit #               :=    data identifier (submitting site)
File of origin       :=    Name of original file.
Comment description  :=    brief title to characterize comments
```

Format of data in the image:

ASCII text.

5.2 Sample Entries in the Directory

```
Image #              :=    1
Image type           :=    COMMENT
Case #               :=    1
Patient name         :=    FALSENAME
Unit #               :=    01-23-456
Comment description  :=    Example of a comment file
```

5.3 Sample Image File

This is an example of comment text. It can be used to transmit information about the case being transmitted, or anything else.

Many such "images" can be put on one tape, and more than one can apply to any one case. The directory entry "comment description" is a useful way of indicating what is in this file so that the recipient of the tape can decide on the urgency with which to approach the task of looking at the comment.

---

6. CT SCAN, MRI AND ULTRASOUND IMAGES

CT scans, MR images and ultrasound images (hereafter referred to as Patient Images or PI) are two

dimensional arrays of 8 or 16 bit numbers. In the case of the 16 bit numbers, they are to be packed most significant byte first in accordance with the AAPM format. Patient Images (PI) are required to have square pixels (size of grid 1 units is the same as the grid 2 units). With the publication of Version 4.00, non-squarePI are now supported. The PI pixel numbers are required to be POSITIVE in the range 0 to 32767 for 16 bit pixels and 0 to 255 for 8 bit pixels - which means that some offset must be added to the Hounsfield (or other) numbers natural to the scanner to ensure that this constraint is complied with. In the case of 8 bit data, the data type is *unsigned byte* which requires that if the 8 bit data is handled as positive and negative values on the submitting system, an offset must be provided to ensure proper order of the pixel values..

To define the CT scale fully the user is required to provide two constants, CT-AIR and CT-WATER which are, respectively, the values of the transmitted data which correspond to air and water. If, for example, the user added 1000 to CT numbers of a scanner which has -1000 to +3071 as the normal range of CT numbers, the constants would have the values CT-AIR = 0 and CT-WATER = 1024 when the CT values are offset by +1000. The CT offset should be large enough that no negative binary values are written in the CT data and no CT value is greater than 32767.

A new keyword (IMAGE SOURCE) has been added to provide for descriptive information about the source of the CT/MR/US images. **When this optional keyword is not used** the source is assumed to be the image acquisition device (i.e. scanner, ultrasound unit, etc.). When this keyword is used, the only allowed value for the key value is SECONDARY CAPTURE. Using SECONDARY CAPTURE assumes that the images were acquired by some type of frame capture, either digitizer or screen capture. Several heretofore required keywords become optional when the IMAGE SOURCE keyword is used. The CT AIR and CT WATER values are no longer required when SECONDARY CAPTURE is the image source. Also, the pixels are allowed to be rectangular when SECONDARY CAPTURE is the image source.

Many scanners have an imperfect CT scale, so that air and water do not have their nominal values. This can be corrected by supplying the correct values (rather than the nominal values) for CT-AIR and CT-WATER. Non-linear behavior is possible. If the user has corrected for this the keyword/value "CT *scale := Linearized"* must be provided. If the CT numbers have been transformed to water-equivalent densities the keywords/value "CT *Scale := Water-equivalent"* must be provided. If the CT numbers transmitted should be distrusted above the certain value, that value should be specified with the "Distrust above" keyword.

6.1 Coordinate System and Scan Offsets

The pixel data are to be ordered so that, if a scan is considered to be viewed from the patient's feet, the first pixel would correspond to the upper left hand corner of the scan, subsequent pixels would correspond to the data in the first row going from left to right followed by the pixels of the second and subsequent rows, ending at the lower right hand corner.

A right-handed cartesian coordinate system - referred to as the PATIENT COORDINATE SYSTEM - is superimposed on the scans. *ADD2: The z axis is positive pointing out of the paper, which always points toward the patient's feet. It should be noted that this is DIFFERENT from the IEC patient coordinate system.*

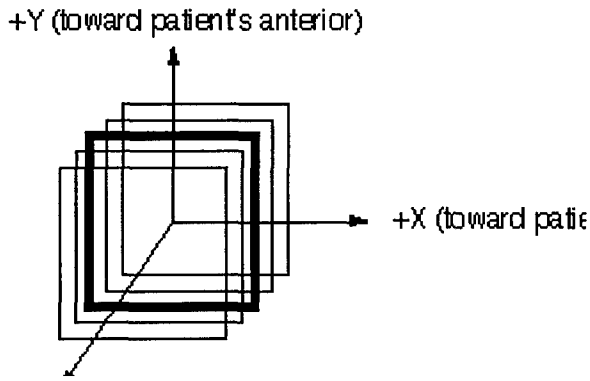


Figure 6.1

Figure 6.1 illustrates the coordinate system. The axes depicted in Figure 6.1 represent a patient who is scanned head first in a supine position. The coordinate system is more accurately described as a "hybrid" coordinate system where X and Y are independent upon the patient orientation on an external beam treatment unit couch and the Z coordinate is based on patient scan order. While the Figure 6.1 anatomical labels correspond to the identified axes when scanned head first, supine, the X and Y coordinate axes are actually tied to a treatment couch with +X to the right of the gantry when viewed from the couch and +Y is up toward the ceiling (assumes couch position orthogonal to plane of gantry rotation). The +Z coordinate is always toward the patient's feet independent of their scanning or treatment orientation which may require inverting this coordinate value depending upon the order maintained by the RTP system. With regard to coordinate system for brachytherapy data exchange, the anatomical labels and the corresponding axes identified in Figure 6.1 must be used.

Generally the origin of the patient coordinate system is at the dead center of the CT/MRI/US image (element 160.5, 160.5 of a 320x320 array, for instance where 1 refers to the first pixel in the image). However, offsets of the images are permitted as indicated in the following figure. **Offsets are positive when the displacement is in the indicated directions as in Figure 6.2 (i.e. they are the directional measurement from the patient coordinate system origin in X and Y to the geometric center of the scan).**

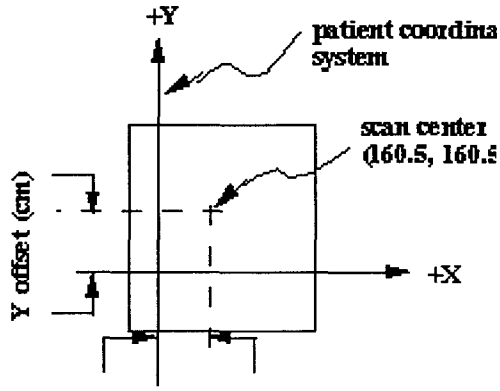


Figure 6.2

Scans must be provided in contiguous order on tape (or in the file set), in order of monotonically

increasing value of the z coordinate. However, a sequence of scans need not be uniformly spaced along the axis normal to the plane of the scans (z axis).

In terms of this coordinate system, CT/MRI/US data are to be stored within the data array in the following manner: The upper left hand corner pixel (least x, greatest y) is first, followed by pixels in the first row (i.e. the x dimension is incremented first), followed by subsequent rows of lesser y value until the bottom right (greatest x, least y) pixel terminates the array. With the exception of some keyword changes, the MRI/US image format is almost identical to that of the CT scan images both in terms of the actual pixel data as well as in the directory structure entries.

6.2 Keywords for Images Used in CT Scan Directory

Required Keywords

Image #	:=	actual image (file) number (see 4.4)
Image type	:=	CT SCAN identifies as CT scan
Case #	:=	1 for first case, 2 for second case, etc.
Patient name	:=	patient identifier
Scan type	:=	TRANSVERSE
CT offset	:=	see text
Grid 1 units	:=	pixel width (cm)
Grid 2 units	:=	pixel height (cm) Must be same as Grid 1 units unless IMAGE SOURCE is used
Number representation	:=	TWO'S COMPLEMENT INTEGER
Bytes per pixel	:=	must equal 2
Number of dimensions	:=	must equal 2
Size of dimension 1	:=	number of rows
Size of dimension 2	:=	number of columns
z value	:=	couch position (cm, + to feet)
x offset	:=	usually 0.0 (cm) [signed x distance from coordinate system's x origin to the geometric center of the CT scan pixel image]
y offset	:=	usually 0.0 (cm) [signed y distance from coordinate system's y origin to the geometric center of the CT scan pixel image]
CT-air	:=	0 (this value is optional when the IMAGE SOURCE is used)
CT-water	:=	1000 (this value is optional when the IMAGE SOURCE is used)

Optional Keywords

Unit #	:=	Unit number or ID
Site of Interest	:=	prostate, etc. as appropriate
Scan description	:=	"contrast study", etc.
Scanner type	:=	GE9800, SIEMENS DRH, etc.
Head in/out	:=	IN, OUT
Position in scan	:=	NOSE UP, NOSE DOWN, LEFT SIDE DOWN, RIGHT SIDE DOWN
Patient attitude	:=	RECUMBENT, SEATED, STANDING
Tape of origin	:=	helps you retrieve your original data
Study number of origin	:=	helps you retrieve your original data
Scan ID	:=	original scan identifier
Scan #	:=	scan # in this sequence
Scan date	:=	use AAPM format (DD, MM, YYYY)
Scan file name	:=	original file name
Slice thickness	:=	in cm.
CT scale	:=	LINEARIZED, WATER-EQUIVALENT
Distrust above	:=	maximum credible CT value
Image Source	:=	SECONDARY CAPTURE

The pixel sizes (Grid 1 or 2 units) are positive for transverse oriented images. All coordinates and linear dimensions are expressed in centimeters.

Format of data in the image file:

Binary data in two's complement integer 0 to 32767.

6.3 Sample Entries in the Directory

Only the first two scans of this data set are shown.

```
Image #                 :=    1
Image Type              :=    CT SCAN
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
CT Offset               :=    1024
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Number of Dimensions    :=    2
Size of Dimension 1     :=    512
Size of Dimension 2     :=    512
Z value                 :=    7.5000
X Offset                :=    0.0000
Y Offset                :=    0.0000
CT-air                  :=    0
CT-WATER                :=    1024
SCAN #                  :=    1
Slice Thickness         :=    0.5000

Image #                 :=    2
Image Type              :=    CT SCAN
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
CT Offset               :=    1024
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Number of Dimensions    :=    2
Size of Dimension 1     :=    512
Size of Dimension 2     :=    512
Z value                 :=    8.0000
X Offset                :=    0.0000
Y Offset                :=    0.0000
CT-air                  :=    0
CT-WATER                :=    1024
SCAN #                  :=    2
Slice Thickness         :=    0.5000
```

and so on for the remainder of the scans.

6.4 Sample Image of Data for CT Scan

Data are in 16-bit, 2's complement, integer representation but are required to be within the 0 to 32767 range. Data is in raster order with the first pixel being the upper left of the image (i.e. the most negative x

coordinate pixel and the most positive y coordinate pixel), the next pixel being just to the right of the first pixel until that raster line is complete, then all remaining raster lines until the last pixel (lower right).

6.5 Keywords for Images Used in MRI/US Scan Directory

Required Keywords

```
Image #                 :=    actual image (file) number (see 4.4)
Image type              :=    MRI or ULTRASOUND
Case #                  :=    1 or Registered case number (numeric only)
Patient name            :=    patient identifier
Scan type               :=    TRANSVERSE
Pixel offset            :=    value added to each pixel to ensure >= 0 for all pixe
Grid 1 units            :=    pixel width (cm)
Grid 2 units            :=    pixel height (cm) Must be same as Grid 1
                              units unless IMAGE SOURCE is used
Number representation   :=    TWO'S COMPLEMENT INTEGER or UNSIGNED BYTE
Bytes per pixel         :=    2 for two's complement or 1 for unsigned byte
Number of dimensions    :=    must equal 2
Size of dimension 1     :=    number of rows
Size of dimension 2     :=    number of columns
z value                 :=    couch position (cm, + to feet)
x offset                :=    usually 0.0 (cm) [signed x distance from
                              coordinate system's x origin to the
                              geometric center of the CT scan pixel image]
y offset                :=    usually 0.0 (cm) [signed y distance from
                              coordinate system's y origin to the
                              geometric center of the CT scan pixel image]
```

Optional Keywords

```
Scan date               :=    use AAPM format (DD, MM, YYYY)
Image Source            :=    SECONDARY CAPTURE
```

The pixel sizes (Grid 1 or 2 units) are positive for transverse oriented images. All coordinates and linear dimensions are expressed in centimeters.

Format of data in the image file:

Binary data in two's complement integer 0 to 32767 or byte 0 to 255.

6.6 Sample Entries in the MRI/US Directory

Only the first two scans of this data set are shown.

```
Image #                 :=    1
Image Type              :=    MRI
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
Pixel Offset            :=    127
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Number of Dimensions    :=    2
Size of Dimension 1     :=    256
Size of Dimension 2     :=    256
Z value                 :=    5.5000
```

```
X Offset                :=    0.0000
Y Offset                :=    0.0000
Scan Date               :=    22, 06, 1999

Image #                 :=    2
Image Type              :=    ULTRASOUND
CASE #                  :=    1
Patient name            :=    BREAST1B
Scan type               :=    TRANSVERSE
Pixel Offset            :=    0
Grid 1 Units            :=    0.0938
Grid 2 Units            :=    0.0938
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Number of Dimensions    :=    2
Size of Dimension 1     :=    256
Size of Dimension 2     :=    256
Z value                 :=    -3.0000
X Offset                :=    0.0000
Y Offset                :=    0.0000
```

and so on for the remainder of the scans.

6.7 Sample Image of Data for MRI/US Scan

Data are either in 16-bit, 2's complement, integer representation but are required to be within the 0 to 32767 range or in 8-bit unsigned byte within 0 to 255. Data is in raster order with the first pixel being the upper left of the image (i.e. the most negative x coordinate pixel and the most positive y coordinate pixel), the next pixel being just to the right of the first pixel until that raster line is complete, then all remaining raster lines until the last pixel (lower right).

---

7. STRUCTURES

Structures are connected sequences of three-dimensional coordinates which define volumes of interest such as the target volume. A "structure" has a variety of attributes, including a "name", "edition number", "color", free text "description", etc.

The organization of the points is that they are grouped together in planes which coincide with planes on which CT scans are centered. A given structure does not have to be defined in all planes in which scans exist, but the planes in which it is defined are contiguous. That is, no planes are "skipped".

Within a given plane, a structure will consist of one or more "segments" (usually just one). Each segment is a sequence of at least four (4) points which are connected and the last and first points must be the same (that is, the segment is "closed"). These points define a generally irregular curve which lies on the surface of the volume being defined. All segments need not have the same number of points. Segments in contiguous scans are assumed to be connected in some way so as to form the surface of the volume. The reason for permitting more than one segment per plane is so that Y-shaped or O-shaped structures may be defined.

The current definition of structures is tied closely to a scan sequence, paralleling what is currently done in

most programs. More general definitions, requiring a more general data structure, may be needed in future. The keyword/value sequence "Structure format:=Scan-based" shall be included to permit subsequent expansion.

The following figure suggests how the components of a structure are arranged. The coordinates are in centimeters and are relative to the PATIENT COORDINATE SYSTEM defined above (Figure 7.1).

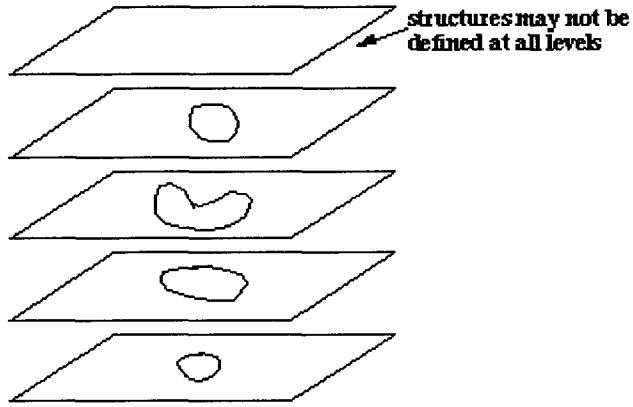


Figure 7.1

The data storage in a structure's image is "defined" through the example in Section 7.3. The data are placed in the buffer in the following order:

```
Number of levels (total # of scans)
  Scan number (=1 for first scan, etc.)
    Number of segments in this level (scan)
      number of points in first segment
      triplets of (x, y, z) coordinates, one per point, last=first
      number of points in second segment
      triplets of (x, y ,z) coordinates, one per point, last=first
```

Scan number (=2 for second scan,) Number of segments in this level (scan) number of points in first segment triplets of (x, y, z) coordinates, one per point, last=first number of points in second segment triplets of (x, y ,z) coordinates, one per point, last=first

Comments may be embedded in the data file if enclosed in quotes as documented in 3.2.1.

Scans must be contiguous on tape. This supports the data structure of structures which presumes that sequential contours are associated with sequential (contiguous) scans ordered monotonically with increasing value of the associated z coordinate. **All scans must be referenced (in order) even if the structure does not exist in a particular slice.** In this case the only data in the file will be the Scan # and the Number of Segments (0). See Section 7.3 for an example of this.

7.1 Keywords for Images Used in Directory

Required Keywords

```
Image #                    :=    actual image (file) number (see 4.4)
Image type                 :=    STRUCTURE
Case #                     :=    1 for first patient,
                                 2 for second patient, etc.
Patient name               :=    patient identifier
```

```
Structure name              :=   structure identifier (liver, heart,
                                 etc.)
Number Representation       :=   CHARACTER
Structure format            :=   SCAN-BASED
Number of scans             :=   same as # CT scans in the exchange
                                 file set
```

Optional Keywords

```
Maximum # scans             :=   100 or system limit (may be set to
                                 Number of scans value)
Maximum points per segment  :=   200 or system limit
Maximum segments per scan   :=   2 or system limit
Unit #                      :=   unit number or ID
Writer                      :=   person responsible for this data
Date written                :=   AAPM format date (DD, MM, YYYY)
Structure edition           :=   1 or higher
Structure color             :=   RED, GREEN, BLUE, YELLOW, MAGENTA,
                                 CYAN OR WHITE
Structure description       :=   Free form text
Study # of origin           :=   for submitting institution's
                                 identification
Orientation of structure    :=   TRANSVERSE
```

Format of data in the image:

ASCII Text

7.2 Sample Entries in the Directory

```
Image #                     :=   56
Image Type                  :=   STRUCTURE
Case #                      :=   1
Patient Name                :=   BREAST1B
Structure Name              :=   EXTERNAL
Number Representation       :=   CHARACTER
Structure Format            :=   SCAN-BASED
Number of Scans             :=   55
Maximum # scans             :=   128
Maximum Points per Segment  :=   200
Maximum Segments per Scan   :=   4

Image #                     :=   57
Image Type                  :=   STRUCTURE
Case #                      :=   1
Patient Name                :=   BREAST1B
Structure Name              :=   TARGET
Number Representation       :=   CHARACTER
Structure Format            :=   SCAN-BASED
Number of Scans             :=   55
Maximum # scans             :=   128
Maximum Points per Segment  :=   200
Maximum Segments per Scan   :=   4
```

7.3 Sample Image Data for Structure

```
"NUMBER OF LEVELS"   55
"SCAN # "   1
"# OF SEGMENTS "   0
"SCAN # "   2
"# OF SEGMENTS "   0
```

```
"SCAN # "    3
"# OF SEGMENTS "    0
"SCAN # "    4
"# OF SEGMENTS "    0
(8 structure scan numbers omitted here)
"SCAN # "   13
"# OF SEGMENTS "    0
"SCAN # "   14
"# OF SEGMENTS "    0
"SCAN # "   15
"# OF SEGMENTS "    0
"SCAN # "   16
"# OF SEGMENTS "    0
"SCAN # "   17
"# OF SEGMENTS "    0
"SCAN # "   18
"# OF SEGMENTS "    1
"# OF POINTS    "   15
  -6.440,    5.850,   -3.500
  -6.230,    5.890,   -3.500
 (11 coordinate triplets omitted here)
  -6.660,    5.620,   -3.500
  -6.440,    5.850,   -3.500
"SCAN # "   19
"# OF SEGMENTS "    1
"# OF POINTS    "   32
  -6.260,    7.190,   -3.000
  -6.350,    7.240,   -3.000
  -6.350,    7.240,   -3.000
(28 coordinate triplets omitted here)
   -6.260,    7.190,   -3.000
"SCAN # "   20
"# OF SEGMENTS "    1
"# OF POINTS    "   27
  -7.590,    7.580,   -2.500
  -7.300,    7.690,   -2.500
```

etc.

---

8. BEAM GEOMETRY

Beam geometry's are to be be transferred as one data file per beam with the data file containing the information defining the beam aperture information. Some of the formalism herein is borrowed from the Foundation Library Specification and Virtual Machine Platform (VMP) Specification document from the Radiotherapy Treatment Planning Tools Collaborative Working Group (Tech. Report 91-1, Ira Kalet, Ph.D., Radiation Oncology Department RC-08, University of Washington, Seattle, WA 98125, USA).

There are several pieces of information required to be able to build a "treatment plan" using beam geometries. The first is the particular beam definition itself, including the prescribed dose per treatment of this field as well as the number of treatments delivered. Second is the identification of other beams that are treated in the same fraction(s) with this beam so that fractionation information may be obtained. Additionally, the grouping of all beams which are treated (or may be treated) is also provided so that a composite of all treatments may be reconstructed and the fractionation data with it.

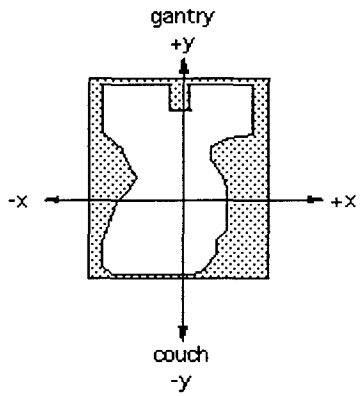
The origin of the beam coordinate system (for the aperture definition) is defined with the treatment machine's collimator rotated to the neutral position (e.g. new Varian machines allow collimator angles

from 90 to 270 degrees with 180 being the "neutral" position) and the gantry angle set such that the beam is pointed at the floor (down). The +y axis is toward the machine gantry when viewing along the beam's central axis with the gantry toward the top of your head. The +x axis is to your right when using the same view. All coordinates for apertures are in this unrotated coordinate system. All collimator, gantry and couch angles are defined to be zero for the gantry pointed down, the couch longitudinal axis orthogonal to the plane of gantry rotation and the collimator's +y axis is along the couch's longitudinal axis and is pointed toward the gantry. See Figure 8.1.

Angles are positive in the counter-clockwise (CCW) direction. CCW is defined from the above view for collimator and couch rotation and as viewed when looking into the gantry from the couch for the gantry rotation. The assumed patient orientation is with head to gantry. If the patient is being treated with foot to gantry, the keyword HEAD I/OUT must be used with a key value of OUT. The HEAD IN/OUT keyword may also be standardly used for head in as well but is required for head out treatments. For example, a right lateral beam for a patient oriented with head to gantry will have a gantry angle of 90 degrees, while the gantry angle would be 270 degrees for a right lateral beam with the patient's feet toward the gantry.

Beam shapes may be specified by MLC settings, contours for custom portal blocks and, for use with Peregrine and similar systems, by transmission maps. For a simple block, or MLC field, the map points inside the open regions of the beam would have a transmission value of 1.000. The map points under the MLC leafs or block will have transmission values appropriate with recommendations and/or requirements of receiving system. The 3D QA Center does not support the use of transmission maps for block specification.

Note that dynamic, conformal therapy and intensity modulation are not explicitly accounted for here anc are left for future expansion.



View is from beam source along the central axis with the beam pointing at the floor (gantry angle = 0 and collimator angle = 0)

Figure 8.1

8.1 Data Contained in the Image File

The data in the image file is as follows:

- Coordinate of machine isocenter (or nominal source reference point distance for machines without a rotational center) in centimeters in the patient coordinate system.
- Collimator setting(s) for the x jaws (e.g. 25.0 for SYMMETRIC, or 11.0, 14.0 for ASYMMETRIC -- negative values are for a jaw that crosses and blocks the central axis)

- Collimator setting(s) for the y jaws (e.g. 25.0 for SYMMETRIC, or 11.0, 14.0 for ASYMMETRIC -- negative values are for a jaw that crosses and blocks the central axis)

ADD3: For asymmetric collimator specifications the jaw which normally resides to the left (negative X in beam coordinates) or to the bottom (negative Y in beam coordinates) is specified first followed by the opposing jaw position. Again, note that a negative coordinate for an asymmetric jaw value implies that it has crossed the central ray. For instance, an asymmetric collimators setting of 11.0, 14.0 for X and -2.0, 8.0 for Y results in a 25.0 cm wide by 6.0 cm long rectangle which is centered at +1.5 cm in X and +5.0 cm in Y.

For APERTURE TYPE := COLLIMATOR

- No additional data is included (yes this does seem a bit wasteful of space but should be an anomaly for conformal therapy). However, an empty file of minimal length must be provided to maintain consistency and order in the format. In the case of conformal therapy (for which this format was extended) this empty file is improbable.

For APERTURE TYPE := BLOCK

- # of block contours (the following are repeated for each contour)
- Block type (0 = aperture definition, 1=block definition) for block. Only one aperture is allowed per beam while multple blocks are allowed.
- Block fractional transmission under block (must be less than 1.00)
- # of block coordinate pairs (must close the contour) for block
- Coordinate pairs for block contour

For APERTURE TYPE := MLC_X or MLC_Y

- # of leaf pairs
- Center coordinate for each leaf pair in increasing coordinate (y values for MLC_X, x values for MLC_Y)
- Thickness of each leaf pair in cm.
- Extension coordinates for each leaf pair where a negative value denotes extension across the central axis (minimum x or y, maximum x or y leaf position).
- NOTE that most currently available commercial MLC collimators are MLC_X only. Generally MLC_Y or MLC_XY is not appropriate for use

For APERTURE TYPE := MLC_XY

- # of leaf pairs in x
- Center coordinate for each leaf pair in increasing coordinate (y values)
- Thickness of each x leaf pair in cm.
- Extension coordinates for each x leaf pair where a negative value (x) denotes extension across the central axis.
- # of leaf pairs in y
- Center coordinate for each leaf pair in increasing coordinate (x values)
- Thickness of each x leaf pair in cm.
- Extension coordinates for each y leaf pair where a negative value (y) denotes extension across the central axis (minimum x or y, maximum x or y leaf position).

For APERTURE TYPE := TRANSMISSION_MAP

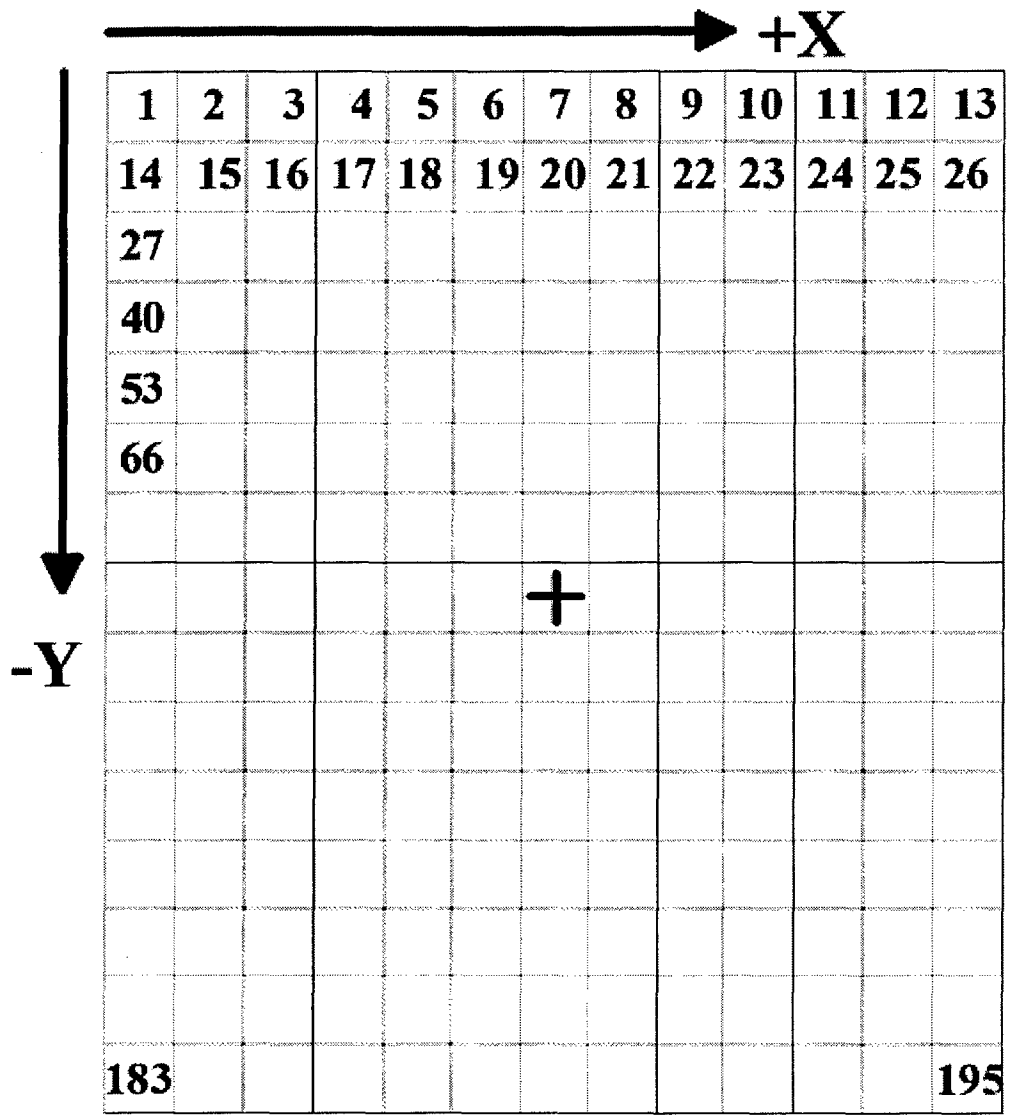
- # of X transmission values (I), # of Y transmission values (J)
- size of square transmission element (cm) (transmission maps are required to use square map elements, but matrix may be rectangular)
- X1, Y1 (starting coordinate in cm of the center of the upper-left map element, -X, +Y in beam coordinates)
- # of transmission value, block thickness pairs (N)
- transmission value #1, block thickness #1 (cm)
- transmission value #2, block thickness #2 (cm)
- .....
- .....
- .....
- transmission value #N, block thickness #N (cm)
- ROW #1 transmission values
- ROW #2 transmission values
- .....
- .....
- .....
- ROW #J transmission values

If blocks are used, only one *aperture definition* is allowed although there is no strict limit on block definitions. This is to prevent system dependent ambiguity which would arise in the case of multiple apertures. The assumption this specification makes is that once a ray from a beam is blocked, it stays blocked. In the case of an aperture, all points outside of the contour are implicitly blocked, therefore they remain blocked.

Transmission Map Description

The transmission map specification involves three primary bits of data. The first is the matrix specification for the map for a rectangular matrix of square transmission elements. This specification includes the size of the square elements, the number of elements in each row and column and the coordinate of the center of the elements (not a corner). Another is a transmission value for the rectangular matrix made up of square elements where the transmission numbers represent the appropriate transmission value for the block material used according to the requirements of the receiving system. Points not under any block material will have a transmission value of 1.00 with lesser values for points under attenuators (MLC or block). Lastly, a map of block material thickness versus transmission value to define the physical characteristics of the portal shaping device. This implies that there are only as many distinct transmission values as are defined in the list of thicknesses and transmission values.

The order of the data in the file (for the transmission map) is identical to that used for compensating filters. The transmission values are specified in raster order from the most negative X and most positive Y coordinate (in beam coordinates) to the most positive X coordinate and most positive Y coordinate for the first row, followed by each subsequent row (see Figure 8.2).



Order of Transmission Map Information

Figure 8.2

An example of the data in a transmission map beam data file is as follows. Note that the isocenter and collimator information is first in the file, followed by the transmission map followed by any compensator information.

```
"# of X Elements" 101, "# of Y elements" 85
"Size of square matrix element (cm)" 0.15
"Center of X1, Y1 (cm)" -7.5, 6.3
"# of transmission value thickness pairs" 2
"Pair #1" 1.0000, 0.0
"Pair #2" 0.0325, 8.1
"NX" 8, "NY" 6
"ROW #1"0.0325, 0.0325, 0.0325, 0.0325, 0.0325, 0.0325, 0.0325, (etc)
"ROW #2"0.0325, 0.0325, 0.0325, 1.0000, 1.0000, 1.0000, 1.0000, (etc)
Compensating filter information follows.
```

ADD4:**Compensating Filters**

Compensating filters may be specified in an abbreviated or extended form. The abbreviated form is identical to that used for Version 3.22 of this Specification. That uses only a "flag" to indicate that a compensating filter was used through use of the COMPENSATOR keyword and the appropriate keyvalue (NONE, 1D-X, 1D-Y, 2D, or 3D).

The extended form allows for either construction or attenuation information to be provided using the new keyword COMPENSATOR FORMAT. The key values available for use with this keyword are: THICKNESS, ATTENUATION, TISSUE, or NONE. Using the NONE keyvalue is identical to the results obtrained through using only the COMPENSATOR keyword with the appropriate flag and not including the COMPENSATOR FORMAT keyword (identical to the Version 3.22 capability). The other key values (THICKNESS, ATTENUATION and TISSUE) indicate that a matrix of compensating filter construction is being supplied in the beam data file. This matrix specification and data is in the data file following all other beam geometry information (isocenter, collimators, blocks and/or MLC specifications). In the case of ATTENUATION, the matrix values are fractional transmission (i.e. 0.25 indicates that 25% of the impinging radiation is transmitted). There is no explicit or implict statement about whether the attenuation values are narrow or broad beam. The matrix values in the data file for THICKNESS indicate the thickness of the construction material in cm. It is assumed that the receiving system has predefined information necessary to appropriately use this information for dose calculation (e.g. construction material). For TISSUE specified compensators, the matrix values correspond to the thickness of unit density tissue which must be accounted for. This generic specification may allow for appropriate interpretation by construction systems or devices.

2D or 3D Compensator Construction Specification

As the only difference between 2D and 3D compensators is the inclusion, or exclusion, of heterogeneity corrections for their design, they are specified in identical fashion as a two-dimensional grid defined at the NOMINAL ISOCENTER DISTANCE specified for the beam in which the delta-x between all columns in the matrix is uniform as is the delta-y between rows, but where the delta-x and delta-y are not required to be equal to each other (but, probably will be). The compensator matrix data is specified in raster order such that the starting coordinate specified is to the upper left (least X and greatest Y matrix element) of the grid (similar to the order of dose matrix values in a transverse plane). Because it is assumed that each matrix element occupies space, the starting coordinate specified (and the coordinates for other elements computed) are in the center of a region of attenuation with width delta-X and length delta-Y. Specifying the center of the matrix element causes the X1, Y1 coordinates to be offset by one-half the delta of the axis from the corner of the physical compensator (toward positive X and negative Y). The data is formatted as follows:

1. NX, NY (integer number of columns and rows)
2. delta-X, delta-Y (floating point interval between columns [greater than 0.0], floating point interval between rows [less than 0.0])
3. X1, Y1 (starting coordinate in cm of the center of the upper-left matrix element, -X, +Y in beam coordinates)
4. beam attenuation coefficient (1/cm) for THICKNESS specifications, or 1.00 for ATTENUATION and TISSUE specifications
5. ROW #1 attenuation or thickness values
6. ROW #2 attenuation or thickness values
7. ...
8. ...
9. ROW #NY attenuation or thickness values

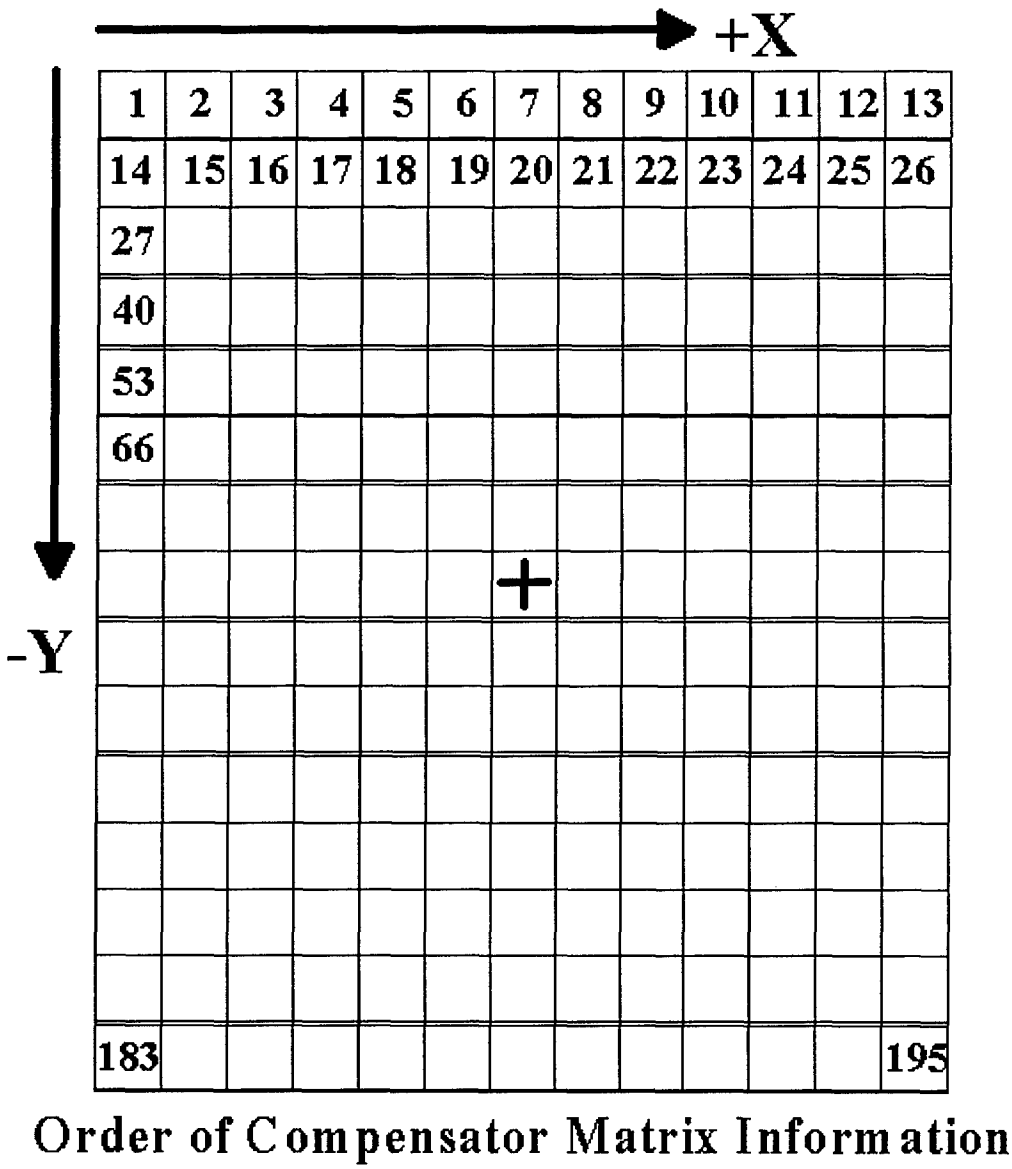


Figure 8.3

Figure 8.3 demonstrates the order of compensating filter data in the data file using the numbers in the individual compensator cells. Note that this is in raster order with a positive delta-X and a negative delta-Y. This figure shows the central ray of the beam through the center of a grid element, however, this is not required and the grid may align in any fashion with the major axes of the beam.

A simple (non-realistic) example of a 2D or 3D compensator construction text file follows. This sample is for a VERY SIMPLE compensator for a SMALL field for a beam with a NOMINAL ISOCENTER DISTANCE of 100.0 cm and for which the compensator matrix elements project to 1.5 cm wide at this distance. The collimator settings are symmetric along both axes and result in a field size of 10.0 cm x 7.0 cm at this same distance. The COMPENSATOR FORMAT is ATTENUATION. For compensating filter specification in thicknesses, it is assumed that the receiving system has some predefined understanding of the material used for construction. This compensator information follows the isocenter, collimator and blocking specification information.

```
"NX" 8, "NY" 6
"delta-X (cm)" 1.50, "delta-Y (cm)" 1.50
"X1, Y1" -7.25, 3.75
"Attenuation value per cm" 1.00
"ROW #1"0.872, 0.880, 0.820, 0.820, 0.850, 0.850, 0.900, 0.900
"ROW #2"0.900, 0.900, 0.820, 0.850, 0.850, 0.850, 0.900, 0.900
"ROW #3"0.900, 0.900, 0.850, 0.850, 0.850, 0.950, 0.950, 0.872
"ROW #4"0.900, 0.900, 0.850, 0.800, 0.900, 1.000, 0.950, 0.872
"ROW #5"0.872, 0.900, 0.850, 0.800, 0.850, 0.950, 0.900, 0.900
"ROW #6"0.872, 0.880, 0.820, 0.820, 0.850, 0.850, 0.900, 0.900
```

The 1D compensator (or custom step-wedge) is more simply specified as it contains only a single array corresponding to the axis across the steps (X or Y). Because the steps of these types of systems are not necessarily regularly spaced, the compensator is specified much like a cumulative histogram plot with each step being specified by a starting beam coordinate (at the NOMINAL ISOCENTER DISTANCE) and a thickness or attenuation value which is considered constant to the coordinate of the next step specified. Note that the type (ATTENUATION, TISSUE or THICKNESS) are handled in the same manner as that for 2D and 3D compensators. The slabs must be specified order of increasing coordinate (X or Y, as appropriate).

1. N (integer number of compensator steps)
2. beam attenuation coefficient (1/cm) for THICKNESS specifications, or 1.00 for ATTENUATION and TISSUE specifications
3. SLAB #1 starting coordinate, attenuation or thickness values
4. SLAB #2 starting coordinate, attenuation or thickness values
5. ...
6. ...
7. SLAB #N starting coordinate, 0

A simple example of a 1D compensator data file entry for a 1D-X compensator specified by THICKNESS follows:

```
"NX" 8
"Attenuation value per cm" 0.967
"SLAB #1 X-coordinate"-10.00, 0.000
"SLAB #2 X-coordinate" -9.00, 0.600
"SLAB #3 X-coordinate" -7.00, 1.200
"SLAB #4 X-coordinate" -3.00, 1.800
"SLAB #5 X-coordinate"  0.00, 2.400
"SLAB #6 X-coordinate"  1.00, 3.000
"SLAB #7 X-coordinate"  3.00, 3.600
"SLAB #8 X-coordinate"  6.00, 4.200
"SLAB #9 X-coordinate"  8.00, 4.800
"SLAB #10 X-coordinate" 10.00, 4.200
"SLAB #11 X-coordinate" 11.00, 0.000
```

There is no extrapolation or extension of compensator information beyond the coordinate values covered by the explicit compensator specification. Specifying a compensator smaller that the open field dimensions on the skin will have indeterminate results.

Following are the keywords for the Beam Geometry definition in the directory file:

8.2 Keywords for Images Used in Directory

Required Keywords

Image #	:=	actual image (file) number (see 4.4)
Image Type	:=	BEAM GEOMETRY
Case #	:=	1 for first case, 2 for second case in file set, etc.
Patient Name	:=	patient identifier
Beam #	:=	Beam number in plan of origin (to index with dose files later)
Beam Modality	:=	X-RAY, ELECTRON, PROTON, NEUTRON, OTHER
Beam Energy(MeV)	:=	Beam energy in MeV
Beam Description	:=	Text Description of beam (i.e. LPO, AP Boost, etc.)
Rx Dose Per Tx (Gy)	:=	ICRU Reference point dose per treatment (generally, isocenter dose)
Number of Tx	:=	Number of treatments using this field
Fraction Group ID	:=	ID to group beams of common fraction
Beam Type	:=	STATIC, ARC
Collimator Type	:=	SYMMETRIC, ASYMMETRIC, ASYMMETRIC_X, ASYMMETRIC_Y
Aperture Type	:=	BLOCK, MLC_X, MLC_Y, MLC_XY, COLLIMATOR, or TRANSMISSION MAP
Collimator Angle	:=	Collimator angle in degrees
Gantry Angle	:=	Gantry angle in degrees (also start angle for an arc beam)
Couch Angle	:=	Couch angle in degrees
Nominal Isocenter Dist	:=	Rotational source-isocenter distance in cm or nominal treatment distance (i.e. 80.0 cm for Co-60)
Number Representation	:=	CHARACTER

Optional Keywords

Plan ID of Origin	:=	Plan ID of beam origin for grouping beams and doses
Aperture Description	:=	Description of beam aperture
Aperture ID	:=	Identifier of Aperture for beam
Wedge Angle	:=	Wedge angle in degrees (required if wedges are used for this beam)
Wedge Rotation Angle	:=	0, 90, 180, 270 (required if wedges are used for this beam) where: 0 - toe of wedge points toward +y beam axis 90 - toe of wedge points toward +x beam axis 180 - toe of wedge points toward -y beam axis 270 - toe of wedge points toward -x beam axis
Arc Angle	:=	Arc angle in degrees (Req'd of ARC Beam Type) it's sign should reflect the stopping gantry angle.
Machine ID	:=	text string uniquely identifying machine parameter set used for dose calculation
Beam Weight	:=	numeric value specifying beam weight used (or to be used) for dose calculation with definition of this value driven by the WEIGHT UNITS keyword
Weight Units	:=	MU, RELATIVE or PERCENT MU is actual monitor unit (or time) setting used for each treatment RELATIVE is the fractional amount of total beam on time for this beam versus the total beam on time PERCENT is the percentage amount of total beam on time for this beam versus the total beam on time

BEAM WEIGHT and BEAM UNITS are both required if either one of them is used

Compensator	:=	NONE, 1D-X, 1D-Y, 2D, 3D where: 1D is a customized step wedge along specified beam axis 2D is a topographic correcting compensator (an Ellis type for instance) 3D corrects for topography and heterogeneity
Compensator Format	:=	THICKNESS, TRANSMISSION, TISSUE or NONE where: THICKNESS indicates the compensator is specified in ray thicknesses in cm TRANSMISSION indicates the compensator is specified in ray transmission values TISSUE indicates the compensator is specified in ray thicknesses in cm of tissue NONE indicates the compensator's construction is not specified (default if this keyword not used for a compensator)
Head In/Out	:=	IN, OUT where: IN specifies this beam treated with the patient's head toward the gantry (prior to any couch rotation), and OUT specifies this beam treated with the patient's head away from the gantry (prior to any couch rotation). **NOTE:** Orientation is assumed to be head in unless otherwise specified. This keyword is required for a foot in treatment.

Format of data in the image file:

ASCII TEXT

8.3 Sample Entries in the Directory

Image #	:=	25
Image Type	:=	BEAM GEOMETRY
Case #	:=	1
Patient Name	:=	Joe Smith
Beam #	:=	1
Beam Modality	:=	X-RAY
Beam Energy(MeV)	:=	18
Beam Description	:=	AP Port
Rx Dose Per Tx (Gy)	:=	1.00
Number of Tx	:=	25
Beam Type	:=	STATIC
Plan ID of Origin	:=	final
Collimator Type	:=	ASYMMETRIC_X
Aperture Type	:=	BLOCK
Aperture Description	:=	AP Portal Large Field
Collimator Angle	:=	0
Gantry Angle	:=	0
Couch Angle	:=	0
Nominal Isocenter Dist	:=	100.0
Aperture ID	:=	AP Port Block
Compensator	:=	1D-Y
Number Representation	:=	CHARACTER
Fraction Group ID:	:=	1
Head In/Out:	:=	IN

8.4 Sample Image of Beam Geometry Data

```
"Isocenter coordinate" 1.0, -2.5, 15.2
"Collimator Setting x" 11.0, -2.5
"Collimator Setting y" 15.0
"# of block contours" 2
"Block #1 type contour encloses open portal" 0
"Transmission under block" 0.03125
"# of block coordinate pairs" 6
-10.5,   7.0,   -3.0,   7.0,  -3.0,  -7.2,  -5.0,  -4.3,  -9.5,  -6.5
-10.5,   7.0
"Block #2 type contour encloses spinal shield" 1
"Transmission under block" 0.03125
"# of block coordinate pairs" 5
-7.5,   7.5,   -5.5,   7.5,  -5.5,  -7.5,  -7.5,  -7.5,  -7.5,   7.5
"Compensating filter data as shown above"
```

Here is a short example of a multi-leaf data file (MLC_X) with asymmetric collimators in x (ASYMMETRIC_X). All coordinates are defined at the *Nominal Isocenter Distance.* Note that words in quotes are to be ignored by the processing program as documented in Section 3.1.2.

```
"Isocenter coordinate" 1.0, -2.5, 15.2
"Collimator Setting x" 11.0, -2.5
"Collimator Setting y" 15.0
"Number of Leaf Pairs" 26
"Leaf center y positions"    -12.5, -11.5, -10.5,  -9.5,  -8.5,  -7.5
 -6.5,  -5.5,  -4.5,  -3.5,  -2.5,  -1.5,  -0.5,   0.5,   1.5,   2.5
  3.5,   4.5,   5.5,   6.5,   7.5,   8.5,   9.5,  10.5,  11.5,  12.5
"Leaf pair thickness"  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
  1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0,   1.0
"Leaf extensions for Y1"   -8.81,  8.81
"Leaf extensions for Y2"   -8.81,  8.81
"Leaf extensions for Y3"   -8.81,  8.81
"Leaf extensions for Y4"   -8.81,  8.81
"Leaf extensions for Y5"   -8.81,  8.81
"Leaf extensions for Y6"    6.86,  6.95
"Leaf extensions for Y7"    7.93,  7.96
"Leaf extensions for Y8"    8.31,  8.26
"Leaf extensions for Y9"    8.31,  8.25
"Leaf extensions for Y10"   8.30,  8.25
"Leaf extensions for Y11"   8.30,  8.25
"Leaf extensions for Y12"   8.30,  8.25
"Leaf extensions for Y13"   8.29,  8.24
"Leaf extensions for Y14"   8.29,  8.23
"Leaf extensions for Y15"   7.91,  7.79
"Leaf extensions for Y16"   7.50,  7.36
"Leaf extensions for Y17"   6.50,  6.92
"Leaf extensions for Y18"   6.68,  6.49
"Leaf extensions for Y19"   6.27,  6.05
"Leaf extensions for Y20"   5.86,  5.62
"Leaf extensions for Y21"   5.45,  5.18
"Leaf extensions for Y22"   5.04,  4.74
"Leaf extensions for Y23"   4.63,  4.31
"Leaf extensions for Y24"  -8.81,  8.81
"Leaf extensions for Y25"  -8.81,  8.81
"Leaf extensions for Y26"  -8.81,  8.81
"Compensating filter data as shown above"
```

9. DIGITAL FILM IMAGES

This image type supports the exchange of digitized simulation films, digitized portal films, on-line portal images, and computed images (i.e. DRR's). The basic information to be included is the pixel data itself and identifiers so that one image may be distinquished from another when multiple images of the same field are used. The pixels themselves are to be transferred in raster order where the first pixel is the upper left pixel of the image with the most rapid change in position with changing pixel is to the right of the image. The last pixel in the image is the lower right.

The film coordinate system is identical to that used for the Beam Geometry images with respect to the x and y offsets and axes. The DRR digital film image is assumed to be aligned with the unrotated collimator. For example, if the pixel image were to be displayed on a monitor with the collimators superimposed, the collimator edges would be rotated (relative to the edges of the display) if the collimator angle is other than 0 degrees (or a multiple of 90 degrees). If DRR's are aligned with the collimator edges, regardless of the collimator rotation, the COLLIMATOR ANGLE keyword must be used and its' value must be the collimator angle for the associated beam. This angle will be assumed to be zero (implying that the film does not rotate with the collimator) unless this keyword and appropriate value are used.

There are parameters which may be included in the directory to describe a digital film which are designed to define the alignment of the image in the associated radiation beam. While these parameters are necessary for any digital film image (particularly for DRR's), which does not have either a fiducial grid or a port outline on it from which such alignment may be derived, they are not generally required for SIMULATOR or PORT image files. Generally, since this alignment information is available for DRR images, such alignment data is required. The affected keywords are: Grid 1 Units, Grid 2 Units, Source Image Distance, X offset, Y offset and Collimator Angle. Where zero (0) is implicit in the image data (for instance, DRR's are generally constructed such that the central ray is in the geometric center of the pixel image) these keywords are not required. For DRR images Grid 1 Units, Grid 2 Units, Source Image Distance are required keywords, while the use of X offset, Y offset and Collimator Angle depend on the context of the image generation as described with the keyword. None of these keywords is required for SIMULATOR or PORT images.

The pixel data is transferred in a fashion similar to the CT pixels, in that they may be 16 bit unsigned integer values whose range is restricted to 0 to 32767 or may be in a range of 0 to 255 for unsigned byte data. The number of bits per pixel acutally containing data may be specified in order to facilitate the use of local packing and display software.

Since it is possible to have multiple images of the same port in one day, the combination of date and film number uniquely identify a film. Generally, the film number will be 1, but multiple images of the same port in a day are supported through this method.

ADD5: In order to facilitate the exchange of digital film images without having an attached beam in a fraction group (for instance a urethrogram film or perhaps orthogonal isocenter verification films without corresponding beams in the treated fraction groups), the BEAM # and BEAM DESCRIPTION keywords have been made optional. The condition to their optional nature is that if they are not used, the FILM DESCRIPTION keyword must be used and vice versa.

9.1 Keywords for Images Used in Directory

Required Keywords

```
Image #                 :=   actual image (file) number (see 4.4)
Image Type              :=   DIGITAL FILM
Case #                  :=   1 for first case, 2 for second case in
```

		file set
Patient Name	:=	Patient Identifier
Film Number	:=	Number of film on particular date (i.e. 1, 2, etc.)
Film Date	:=	Date digital image acquired (DD, MM, YYYY)
Film Type	:=	SIMULATOR, DRR, PORT
Number of Dimensions	:=	2 (always)
Size of Dimension 1	:=	number of rows
Size of Dimension 2	:=	number of cols
Number Representation	:=	TWO'S COMPLEMENT INTEGER (for 2 bytes per pixel) or UNSIGNED BYTE (for 1 byte per pixel)
Bytes per Pixel	:=	1 or 2 (must index with Number Representation)

Optional Keywords

Beam #	:=	Beam number in plan of origin (to tie image with) Required if film belongs to a beam in a submitted fraction group.
Beam Description	:=	Text description of beam generating image Required if film belongs to a beam in a submitted fraction group
Film Description	:=	Text Description of film Required if BEAM # and BEAM DESCRIPTION keywords not used and must be the same identical string for all appropriate films (i.e. AP ISOCENTER, RT LAT ISOCENTER, etc.)
Grid 1 Units	:=	pixel width (cm) (required for DRR's)
Grid 2 Units	:=	pixel length (cm) (required for DRR's)
Source Image Distance	:=	equivalent to TFD (cm) (required for DRR's)
X Offset	:=	X offset from geometric center of image to central ray of the beam (required for DRR's where central ray is not in geometric center of pixel image)
Y Offset	:=	Y offset from geometric center of image to central ray of the beam (required for DRR's where central ray is not in geometric center of pixel image)
Film Source	:=	FILM, ONLINE, COMPUTED
Unit Number	:=	Unit number film image acquired from
OD Scale	:=	Scale factor to convert pixel values to optical density
Bits per Pixel	:=	number of bits actually used for pixel information
Collimator Angle	:=	collimator angle in degrees (reflects the collimator angle for the associated beam) if the edges of the image are parallel to the collimator edges. This is **required only for DRR's** which are aligned with the collimator edges and which do not have the portal outline superimposed on the DRR image. It is not required for DRR's which are aligned with the unrotated collimator or for digitized films or on-line images (SIMULATOR and/or PORT images).

Format of data in the image file:

Binary Data

9.2 Sample Entries in the Directory

```
Image #                 :=    37
Image Type              :=    DIGITAL FILM
Case #                  :=    1
Patient Name            :=    Joe Smith
Beam #                  :=    6
Beam Description        :=    Left Lateral Beam
Film Date               :=    15,11,1993
Film Number             :=    1
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    480
Size of Dimension 2     :=    512
Grid 1 Units            :=    0.215
Grid 2 Units            :=    0.200
Source Image Distance   :=    140.0
X Offset                :=    0.0
Y Offset                :=    2.3
Number Representation   :=    TWO'S COMPLEMENT INTEGER
Bytes per Pixel         :=    2
Film Description        :=    verification simulation film
Film Source             :=    FILM

Image #                 :=    38
Image Type              :=    DIGITAL FILM
Case #                  :=    1
Patient Name            :=    Joe Smith
Beam #                  :=    6
Beam Description        :=    Right Lateral Beam
Film Date               :=    15,11,1993
Film Number             :=    2
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    480
Size of Dimension 2     :=    512
Grid 1 Units            :=    0.215
Grid 2 Units            :=    0.200
Source Image Distance   :=    140.0
X Offset                :=    0.0
Y Offset                :=    2.3
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Film Description        :=    first day port image
Film Source             :=    ONLINE

Image #                 :=    39
Image Type              :=    DIGITAL FILM
Case #                  :=    1
Patient Name            :=    Joe Smith
Film Description        :=    AP Isocenter
Film Date               :=    15,11,1993
Film Number             :=    1
Film Type               :=    SIMULATOR
Number of Dimensions    :=    2
Size of Dimension 1     :=    640
Size of Dimension 2     :=    752
Number Representation   :=    UNSIGNED BYTE
Bytes per Pixel         :=    1
Film Source             :=    FILM
```

9.3 Sample Image of Data for Digital Films

Data may be in 16-bit, 2's complement, integer representation wherein the 2's complement is never really used as the values are required to be in the range of 0 to 32767. The pixel data may also be in unsigned byte data in which case the pixel values are between 0 and 255. Data is in raster order with the first pixel being the upper left-hand pixel in the image.

---

10. DOSE DISTRIBUTIONS

A dose distribution is the result of a calculation of dose at one or more points throughout the patient, for a particular configuration of beams - that is, for a particular "plan". Although in general, one might calculate doses on a completely irregular grid of points this is rarely done in practice and the proposed format is for a fairly regular grid, namely one in which a two dimensional array of points is defined in one or more parallel planes. This format naturally accommodates the computation of doses on a 2-D array of points in each CT scan, and recognizes that such scans may not be at equally spaced intervals. It permits the transfer of dose calculations throughout a volume, or in a single plane - or, indeed, along a line or at a single point. Planes may be other than parallel with the scan sections however, thus supporting calculations in sagittal or coronal planes. At present planes oblique to the major axes of the scans, or arbitrarily located points of calculation are not supported.

The points at which the doses are defined are assigned coordinates within the Patient Coordinate System. We first describe the coordinate definitions for the case of arrays defined in planes parallel to transverse sections (i.e. CT scans), and then indicate some differences when the planes are sagittal or coronal. The number of planes (>=1) and a list of the z-values is specified. Within a plane a rectangular array of points is defined by specifying the x, y coordinates of the upper left hand corner point (as viewed from the patient's feet), the x and y increments per point, and the number of points along the x-axis and along the y-axis. The z values for each plane may be unequally spaced and are therefor individually specified. For transverse planes these z values would normally be identical to those of some or all of the CT sections, but this is not required. The order of the planes should be that of increasing value of z.

To preserve the integrity of the right-handed cartesian coordinate system, some sign conventions **must** be obeyed when sagittal or coronal planes are used. The coordinates for single planes as presented to the observer are as follows:

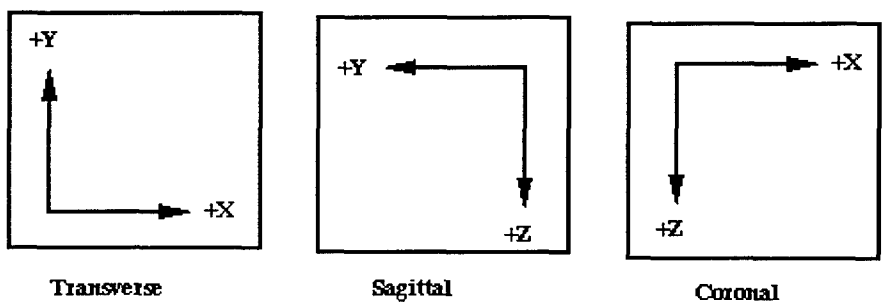


Figure 10.1

These sign conventions have implications for the various parameters as follows:

PARAMETER	TRANS.	SAG.	COR.
(Horiz, vert) coords of points	x, y	z, y	x, z
Usual signs of coords of ULH corner	-, +	+, +	-, -
Usual sign of horizontal increment	+	-	+
Usual sign of vertical increment	-	-	+
Coordinate associated with plane change	z	x	y

Note that these conventions need not be obeyed in the definition of pixel size of CT scans. The vertical size is permitted to be positive for CT scans to conform to conventional usage and is interpreted as the absolute value of the pixel height, rather than a signed increment.

The units in which doses are given are up to the originator of the data. They must be in absolute dose units such as Gray. Relative and Percent are no longer supported in the Dose Units keyword and are now implicit by the inclusion of the Dose Scale keyword, where the Dose Scale keyword is used only if scaling is necessary. The dose values in the image file are multiplied by the Dose Scale value to obtain the Dose Units specified. A 1.00 is assumed for the Dose Scale value unless it is explicitly stated with the Dose Scale keyword.

Dose distributions other than Physical dose, such as of Effective dose, LET, OER or dose uncertainty, are supported through the use of the "Dose Type" keyword.

The Fraction Group ID allows multiple dose distributions to be submitted which will allow for fractionation information to be extracted for both targets and normal tissues and is used to tie Beam Geometry files to a particular dose file (multiple Beam Geometry files may point to the same DOSE file through the Fraction Group ID). All beams contributing dose to this distribution shall have an identical Fraction Group ID in their beam geometry specification.

The Plan ID of Origin is similar to the Fraction Group ID except that instead of being used to tie beam files to the dose file, it is used to tie Seed Geometry files to a Dose file. Unlike the Fraction Group ID, there can only be one Seed Geometry file which points at a given dose file (i.e. there is a one-to-one correspondence).

While both the Fraction Group ID and Plan ID of Origin keywords are listed as optional, when used for RTOG 3D CRT protocol patients, they are required as appropriate.

TEXT (ASCII) DOSE SPECIFICATION

The data storage in a dose image is "defined" through the example given in Section 10.3. The data are placed in the buffer in the following order:

Number of planes (e.g. 19)
Z-coordinate of first constant z plane (for e.g. z = -120.556)
A sequence of real numbers representing the dose at each grid point at this z value. X value (dimension 1) varies faster:

```
  0.000,    0.000,    0.000,    0.000,    0.000,    0.000,    0.000
  4.641,   11.785,   12.031,   10.608,   10.324,   10.258,   10.202
 10.139,   10.125,   10.125,   10.118,    0.000,    0.000,   10.117
 10.132,   10.148,   10.145,   10.145,   10.151,   10.183,   10.234
```

Z-coordinate of second constant z plane (for e.g. z = -119.616)
A sequence of real numbers representing the dose at each grid point at this z value. X value (dimension 1) varies faster:

```
  0.000,    0.000,    0.000,    0.000,    0.000,    0.000,    0.000
  2.011,    9.881,   11.476,   10.608,   10.324,   10.258,   10.202
 10.139,   10.125,   10.125,   10.118,    0.000,    0.000,   10.117
```

BINARY DOSE SPECIFICATION

Doses may also be conveyed in a more succinct, binary format. In order to facilitate this format several additional (otherwise optional) keywords must be specified. Doses using the binary format must meet the following requirements:

- axial dose plane spacing (along Z axist) must be uniform
- the dose values are in two's complement integer format restricted to the positive domain (same as CT pixel values)
- the DOSE SCALE keyword must be used with the appropriate value stated which yields the appropriate dose values (with units) when the matrix values are multiplied by the DOSE SCALE value
- the COORD 3 OF FIRST POINT and DEPTH GRID INTERVAL keywords specifying the smallest (or most negative) Z coordinate and the step between each of the SIZE DIMENSION 3 planes must be specified

The optional keywords required for binary dose specification may not be usedwith text dose specification. The order of the dose matrix elements is identical to that used for the text representation excepting that the Z coordinate is no longer specified (nor is the plane count). As with all binary files, no text is supported in the file (e.g. comments in quotes).

10.1 Keywords for Images Used in Directory

Required Keywords

```
Image #                    :=   actual image (file) number (see 4.4)
Image Type                 :=   DOSE
Case #                     :=   1 for first patient, 2 for second
                                patient, etc
Patient Name               :=   patient identifier

Dose Units                 :=   GRAYS, RADS, CGYS
Orientation of Dose        :=   TRANSVERSE
Number Representation      :=   CHARACTER
Number of Dimensions       :=   3
Size of dimension 1        :=   # horizontal points (>=1)
Size of dimension 2        :=   # vertical points (>=1)
Size of dimension 3        :=   # of planes (>=1)
Coord 1 of first point     :=   x coord (cm) for transverse, etc.
Coord 2 of first point     :=   y coord (cm) for transverse, etc.
Horizontal grid interval   :=   delta-x (cm) for transverse (>0)
Vertical grid interval     :=   delta-y (cm) for transverse (<0)
```

Optional Keywords

```
Dose #                     :=   # identifying this distribution
Dose Type                  :=   PHYSICAL, EFFECTIVE, LET, OER, ERROR
Unit #                     :=
```

```
Writer                          :=
Date written                    :=   date (DD, MM, YYYY)
Dose description                :=   free text
Dose edition                    :=
Plan # of origin                :=
Plan edition of origin          :=
Study # of origin               :=
Version # of program            :=   planning program identification
x coord of normalizn point      :=   cm
y coord of normalizn point      :=   cm
z coord of normalizn point      :=   cm
Dose at normalizn point         :=   should result in units specified
                                     above after being multiplied by
                                     the Dose Scale
Dose error                      :=   NOMINAL, MINIMUM, or MAXIMUM
                                     (for dose range submissions)
Fraction Group ID               :=   ID grouping beams of common
                                     fraction for the doses in this
                                     image file
Number of Tx                    :=   Number of times this fraction
                                     (Fraction Group ID) treated to
                                     achieve total doses in this file
Dose Scale                      :=   Scale factor to convert doses in
                                     image file to absolute doses in
                                     the units specified in the Dose Units.
                                     (assumed to be 1.00 if not specified)
Coord 3 of first point          :=   z coord (cm) for first transverse plane
Depth grid interval             :=   delta-z (cm) between each subsequent
                                     transverse dose plane (>0)

Plan ID of origin                :=  Plan ID of SEED GEOMETRY to required to tie
                                     DOSE file to SEED GEOMETRY file
```

All coordinates and differences are expressed in centimeters in the patient coordinate system.

Format of data in the image:

ASCII text.

10.2 Sample Entries in the Directory

```
Image #                     :=    57
Image Type                  :=    DOSE
Case #                      :=    1
Patient Name                :=    CHEST1C
Dose #                      :=    1
Dose Type                   :=    PHYSICAL
Dose Units                  :=    GRAYS
Orientation of Dose         :=    TRANSVERSE
Number Representation       :=    CHARACTER
Number of Dimensions        :=    3
Size of dimension 1         :=    116
Size of dimension 2         :=    74
Size of dimension 3         :=    101
Coord 1 of first point      :=    -19.3000
Coord 2 of first point      :=    14.3000
Horizontal grid interval    :=    0.3000
Vertical grid interval      :=    -0.3000
Dose description            :=    4FLD CHESTWALL WITH BOLUS
Plan # of origin            :=    26
Fraction Group ID           :=    1
Number of Tx                :=    25
Dose Scale                  :=    0.01
```

10.3 Sample Image of Text Data for Dose

```
"Number of planes is "  101
"Z-coordinate is  " -15.200
   0.000,  0.000,  0.000,  0.000,  0.012,  0.012,  0.013,  0.013
   0.014,  0.015,  0.016,  0.016,  0.017,  0.018,  0.019,  0.019
   0.020,  0.021,  0.022,  0.022,  0.023,  0.024,  0.024,  0.025
   0.026,  0.026,  0.027,  0.028,  0.028,  0.029,  0.029,  0.030
   0.030,  0.031,  0.031,  0.032,  0.032,  0.032,  0.033,  0.033
   0.033,  0.033,  0.033,  0.033,  0.033,  0.033,  0.033,  0.033
   0.033,  0.032,  0.032,  0.032,  0.031,  0.031,  0.031,  0.030
     .       .       .       .       .       .       .       .
     .       .       .       .       .       .       .       .
     .       .       .       .       .       .       .       .
   0.030,  0.029,  0.029,  0.028,  0.027,  0.027,  0.026,  0.026
   0.025,  0.024,  0.024,  0.023,  0.022,  0.021,  0.021,  0.020
   0.019,  0.018,  0.018,  0.017,  0.016,  0.015,  0.014,  0.014
"Z-coordinate is  " -15.000
   0.013,  0.013,  0.012,  0.012,  0.011,  0.011,  0.011,  0.010
   0.010,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
     .       .       .       .       .       .       .       .
     .       .       .       .       .       .       .       .
     .       .       .       .       .       .       .       .
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000,  0.000
   0.012,  0.012,  0.013,  0.013,  0.014,  0.015,  0.015,  0.016
   0.017,  0.018,  0.019,  0.019,  0.020,  0.021,  0.022,  0.022
   0.023,  0.024,  0.024,  0.025,  0.026,  0.026,  0.027,  0.027
```

10.4 Sample Image of Binary Data for Dose

ADD6: The data file for binary formatted dose data consists of two byte integer values restricted to the values from 0 to 32767 packed with the most significant byte first (identical to the numeric format used for CT scans) written in raster order for each axial dose plane. Each subsequent axial plane's dose values are required to be in order of increasing Z coordinate. Any padding required for buffering (for tape writing only) is required only after the last dose point of the last axial plane is written to the file.

---

11. DOSE-VOLUME HISTOGRAMS

Dose-volume histograms (DVH) provide a "pre-digestion" of the doses provided in a 3-D dose distribution with corresponding anatomic structures. While there are several different methods which may be used to display the DVH data, the underlying data is the same: A bin of dose range and a volume associated with the dose range. DVH's are transferred as one structure per image file.

The data in the image file itself is simply an array of doublets where the first value in the doublet is the lower end of the dose bin and the second value is the volume associated with the dose bin. The doses may be in either absolute dose or percent dose and may be converted back and forth using directory information. The volume may be in units of percent or of cubic centimeter (cc) and may be converted back and forth with the additional information available in the directory information for the image file. The dose bins are required to be uniformly spaced and included in the data file from zero dose to the highest dose for which any non-zero volume is identified and no gaps are allowed.

The scaling of relative or percent doses or volumes are performed by multiplying the relative dose or volume value by the appropriate scale value.

11.1 Keywords for Dose-Volume Histograms Used in Directory

Required Keywords

```
Image #                 :=   actual image (file) number (see 4.4)
Image Type              :=   DOSE VOLUME HISTOGRAM
Case #                  :=   1 for first case, 2 for second case
                             in file set
Patient Name            :=   Patient Identifier

Structure Name          :=   name of structure
Dose Units              :=   GRAYS, CGYS, RADS
Dose Type               :=   ABSOLUTE, PERCENT, RELATIVE
Volume Type             :=   ABSOLUTE, PERCENT, RELATIVE
Number of Pairs         :=   Number of dose/volume pairs in image
                             file
Maximum # Pairs         :=   Maximum number of dose/volume pairs
                             allowed
Number Representation   :=   CHARACTER
Plan ID of Origin       :=   ID of plan DVH's calculated from.
                             Indexes with beams and dose
                             distributions.
```

Optional Keywords

```
Dose Scale              :=   Scales percent or relative dose to
                             absolute dose (Required if dose type
                             is not ABSOLUTE)
Volume Scale            :=   Scales percent or relative volume
                             to cc's (Required if volume type is
                             not ABSOLUTE)
Date of DVH             :=   Date DVH calculated (DD, MM, YYYY)
```

Format of data in the image file:

ASCII TEXT

11.2 Example of Dose-Volume Histogram Directory Entries

```
Image #                 :=   39
Image Type              :=   DOSE VOLUME HISTOGRAM
Case #                  :=   1
Patient Name            :=   Joe Smith
Structure Name          :=   Rectum
Plan ID of Origin       :=   final
Dose Units              :=   GRAYS
Dose Type               :=   ABSOLUTE
Volume Type             :=   RELATIVE
Volume Scale            :=   203.1
Number of Pairs         :=   100
Maximum # Pairs         :=   1001
Number Representation   :=   CHARACTER
Date of DVH             :=   15,11,1993

Image #                 :=   40
Image Type              :=   DOSE VOLUME HISTOGRAM
Case #                  :=   1
Patient Name            :=   Joe Smith
```

```
Structure Name          :=    PTV
Plan ID of Origin       :=    final
Dose Units              :=    GRAYS
Dose Type               :=    ABSOLUTE
Volume Type             :=    RELATIVE
Volume Scale            :=    203.1
Number of Pairs         :=    100
Maximum # Pairs         :=    1001
Number Representation   :=    CHARACTER
Date of DVH             :=    15,11,1993
```

11.3 Example of Dose-Volume Histogram Image File

```
"Minimum Bin Dose,  Fractional Volume"
  0.00, 0.05
  1.00, 0.00
  2.00, 0.06
    . . . .
    . . . .
    . . . .
100.00, 0.00
```

Note that the volume associated with each bin dose is that volume which explicitly falls into that dose bin (hence the zero volume values for 1.00 Gy above sandwiched between the 0.00 Gy and 2.00 Gy bins.

---

12. SEED GEOMETRY

Seed geometry files are used to convey the geometric distribution of permanently implanted I125 or Pd103 seeds. These seed distributions may be indexed with an image data set (CT, MRI or Ultrasound), or may be independent of any image set. The information provided in this file should be adequate to calculate the dose distribution with minimal modification of the incoming data by the receiving institution. Multiple seed distributions are only supported in a single file set if they comprise the complete implant in which varying seed activities and/or types are used in the same implant.

NOTE: It is assumed that if any image files (CT/MR/US) are contained within the same digital file set, that the seed coordinates are consistent with the coordinates of the images (i.e. the seeds are registered with the image set). If there are no images with which the seed coordinates are registered, then no image files are allowed to be provided in the same digital file set. This is to simplify the specification of registered versus unregistered seed coordinates.

The fundamental information contained in the directory entries for a Seed Geometry file are:

- Free text identification of the seed model and/or manufacturer to be able to distinguish between the differing characteristics of seeds of various manufacture;
- The isotope for the seeds (restricted to I125 or PD103 for this version of the exchange;
- The strength of the seeds on the day of implant (all seeds are expected to have the same activity +/- the deviation of the batch;
- The units of seed strength specified;
- The date of the implant;
- The number of seeds **identified** in the implant (note that these numbers may differ from pre-plan to post-plan);
- A plan ID string to differentiate pre- and post-plans.

The data file associated with the directory entries consists of only coordinate triplets (in cm) for each of the number of seeds specified in ASCII (text) format.

12.1 Keywords for Seed Geometry Used in Directory

Required Keywords

```
Image #                 :=   actual image (file) number (see 4.4)
Image Type              :=   SEED GEOMETRY
Case #                  :=   1 (or registered case number)
Patient Name            :=   Patient Identifier

Seed Model              :=   model identifier or manufacturer of seed
Isotope                 :=   I125 or PD103
Seed Strength           :=   value corresponding to strength units specified
Strength Units          :=   MCI or CGYCM2PERHR
Date of Implant         :=   date (DD, MM, YYYY)
Number of Seeds         :=   Number of seeds in image file (implant)
Number Representation   :=   CHARACTER (format of data in data file)
Plan ID of Origin       :=   ID of plan seed distribution from
                             Indexes with dose distributions.
```

Format of data in the image file:

ASCII TEXT

12.2 Example of Seed Geometry Directory Entries

```
Image #                 :=   42
Image Type              :=   SEED GEOMETRY
Case #                  :=   1
Patient Name            :=   Joe Smith

Seed Model              :=   6711
Isotope                 :=   I125
Seed Strength           :=   0.43
Strength Units          :=   MCI
Date of Implant         :=   23, 06, 1999
Number of Seeds         :=   27
Number Representation   :=   CHARACTER
Plan ID of Origin       :=   Preplan



Image #                 :=   44
Image Type              :=   SEED GEOMETRY
Case #                  :=   1
Patient Name            :=   Joe Smith
Seed Model              :=   Model 2
Isotope                 :=   I125
Seed Strength           :=   0.38
Strength Units          :=   MCI
Date of Implant         :=   23, 06, 1999
Number of Seeds         :=   63
Number Representation   :=   CHARACTER
Plan ID of Origin       :=   Actual Plan
```

12.3 Example of Seed Geometry Image File

```
"          X (cm),  Y (cm),  Z (cm)"
"Seed #1"    0.00,    0.05,    5.00
"Seed #2"    0.00,    0.05,    5.90
"Seed #3"    0.00,    0.05,    7.20
"Seed #4"    0.00,    0.05,    8.10
   . . . .
   . . . . (intervening 80 seeds not shown)
   . . . .
"Seed #85"    3.00,    3.25,   4.70
```

Document maintained by William B. Harms, Sr. and Walter R. Bosch

Last modified: Thursday, November 04, 1999 10:30:57

Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) QA Facility Questionnaire

Please type this form.

ITEMS REQUIRED BEFORE YOU CAN ENTER CASES ON EACH RTOG TIPPB PROTOCOL:

- Acquire this Facility Questionnaire document from http://rtog3dqa.wustl.edu contemporaneously with completing it and forward the completed form with all required attachments and the requisite Dry Run test data for each prostate brachytherapy protocol you wish to become qualified to participate in to:

  James A. Purdy, Ph.D.
  RTOG 3D Quality Assurance Center
  Washington University
  510 S. Kingshighway Blvd.
  St. Louis, MO 63110

- Demonstrate capability of digital data exchange with the RTOG 3D QA Center and understanding of protocol requirements via the Protocol specific Dry Run Test including (see protocol specific Dry Run Guide published on the 3D QA Center's web site at http://rtog3dqa.wustl.edu):
  1. Patient CT data
  2. Contours – organs at risk and protocol required gross tumor volume(s) (GTV), clinical target volume(s) (CTV), planning target volume(s) (PTV), evaluated target volume(s) (ETV).
  3. 3D dose distribution data.
  4. Source type, seed model, source strength, and position.
  5. Dose-volume histograms for plan.
  6. Axial, sagittal and coronal hard copy isodoses through center of GTV (in absolute dose).
  7. Protocol specific Dry Run T2 Form (different from standard T2 form, available only from 3D QA Center's web site).

- If you intend to submit your digital patient data via the internet, please contact Mr. William Harms at (314) 362-2648 to establish an ftp account for your facility on the 3D QA Center's ftp server (castor.wustl.edu).

I. General Information

Please complete this questionnaire and submit it and the requested supporting physics and dosimetry documents to the RTOG 3D QA Center for each Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) protocol you wish to become qualified to participate in. These data will help assure the RTOG 3D QA Center that each institution has committed proper facilities and effort to this modality.

In addition to this documentation, a protocol specific Dry Run test must be successfully completed to qualify for each study. The Dry Run test should be concurrently developed with the completion of this Questionnaire to facilitate your qualification to participate in the selected protocol. The protocol specific Dry Run Guidelines must be obtained from the RTOG 3D QA Center's Web site (http://rtog3dqa.wustl.edu).

RTOG Protocol #: _____ **RTOG Institution #:** _____

If Affiliate, Name of Member Institution: _____

Responsible Radiation Oncologist

Name: _____

Address: _____

_____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Urologist

Name: _____

Address: _____

_____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Medical Physicist

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Dosimetrist

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Ultrasonographer

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

Responsible Research Associate (Data Manager)

Name: _____

Address: _____

(if different) _____

_____

City: _____ State: _____ Zip Code: _____

Phone #: _____ FAX #: _____

Email Address: _____

II. Experience of personnel:

A. How many TIPPB implants have been performed by the above named radiation oncologist: _____

B. Over what time period has this experience been gained: _____ years _____ months

C. How many TIPPB implants have been preplanned by ultrasound and evaluated with a post implant CT, by the above named physician and physicist: _____

D. Over what time period has this experience been gained: _____ years _____ months

III. TIPPB Equipment (to be used for protocol patients)

A. Ultrasound Unit

1. Vendor/Model:

B. CT Scanner

1. Vendor/Model:

C. MR Scanner (optional)

1. Vendor/Model:

D. 3D Treatment Planning System

1. Vendor/Model:
2. If developed "in-house", please check ☐ and attach a description.
3. Do your ^{125}I dose calculations agree with TG-43 to within ±5% from 5-70 mm: ☐ Yes : ☐ No
4. Confirm that the dose calculational matrix is no larger than 2mm x 2mm x the axial slice width: ☐ Yes : ☐ No
5. Confirm that planning system can display/generate hardcopy of superimposed isodose distributions on 2D CT images (axial, saggital, and coronal planes): ☐ Yes : ☐ No
6. Confirm that planning system is capable of computing & displaying dose-volume histograms: ☐ Yes : ☐ No
7. Confirm that planning system is capable of transmitting data to the 3DQA Center electronically: ☐ Yes : ☐ No

E. Sources

1. Source Type:	Vendor/Model:
2. Source Type:	Vendor/Model:

IV. Quality Assurance Procedures: (attach the following)

A. Source Strength Verification: Submit a description of the procedures followed to verify the calibration of the sources. Include the following:

- Description of dosimeter system (make and Model of chamber and electrometer)
- Confirmation of traceability to NIST
- QA procedures to verify calibration of dosimeter has not changed
- Measurement technique
- Calculation technique, including conversion of the above standard into the source specification units used by your treatment planning computer.
- Frequency of calibration

B. Source Accounting:

- Describe the procedures used to account for all seeds at the time of implant and to assure that the number implanted is used in the dose calculation.
- Also, discuss techniques used to avoid identifying the same source on multiple slices.

C. Dosimetry Procedures:

- Describe any hand calculations done to verify the accuracy of the computer generated treatment plan.
- Describe any other procedures followed to assure that the dose calculations are in accordance with the requirements of the protocol.

D. Imaging Procedures:

- Describe how the imaging capability of the equipment (ultrasound, fluoroscopy, CT or MRI) used to perform prostate implants was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.

E. Other QA Procedures:

- Describe any other quality assurance procedures pertinent to the study objectives.

Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB) Quality Assurance Guidelines

I. Purpose:

A. To establish quality assurance (QA) guidelines for the conduct of low-dose rate transperineal interstitial permanent prostate brachytherapy (TIPPB) multi institutional cooperative group studies.

II. Background

A. Preliminary reports of the success of TIPPB in controlling early stage prostate cancer with few complications have heightened the interest of the medical community. Controlled, prospective multi-institutional trials to validate and investigate the efficacy of this procedure have become a goal of the RTOG. The 3DQA center has expanded its mission to insure the scientific soundness of these trials. The 3DQA Center performs this function through (1) individual and institutional credentialing, (2) establishment of procedural standards, and (3) centralized quality assurance review of case submissions.

B. A partial list of references that describe the procedure and appropriate quality assurance for prostate implantation are listed below.

1. Blasko, JC, et al. Brachytherapy and organ preservation in the management of carcinoma of the prostate. Sem. Radiat. Oncol. 3:240-249, 1993.

2. Grimm, PD, et al. Ultrasound-guided transperineal implantation of iodine125 and palladium-103 for the treatment of early stage prostate cancer; technical concepts in planning, operative technique and evaluation. Atlas Urol. Clin. North Am. 2:113-125, 1994.

3. Wallner, K, et al. Dosimetry guidelines to minimize urethral and rectal morbidity following transperineal I-125 prostate brachytherapy. Int J Radiat Oncol Biol Phys, 32:465-471, 1995.

4. Stock, RG, et al. A dose response study for I-125 prostate implants. Int J Radiat Oncol Biol Phys, 41:101-108, 1998.

5. Prestidge, BR, et al. Timing of computed tomography-based post-implant assessment following permanent transperineal prostate brachytherapy. Int J Radiat Oncol Biol Phys, 40:1111-1115, 1998.

6. Bice, WS, et al. Centralized multi-institutional post-implant analysis for interstitial prostate brachytherapy. Int J Radiat Oncol Biol Phys, 41:921 927, 1998.

7. Nath, R, et al. Dosimetry of interstitial brachytherapy sources: recommendations of the AAPM Radiation Therapy Committee Task Group No. 43. Med Phys 22(2):209-234, 1995.

8. Nath, R. et al. Code of practice for brachytherapy physics: report of the AAPM Radiation Therapy Committee Task Group No. 56. Med Phys 24:1557-1598, 1997.

9. Kubo, H.D., Coursey, B.M., Hanson, W.F., Kline, R.W., Seltzer, S.M., Shuping, R.E., and Williamson, J.F.: Report of the Ad Hoc Committee of the AAPM Radiation Therapy Committee on 125-I Sealed Source Dosimetry. Int. J. Radiat Oncol Biol Phys. 40(3):697-702, 1998.

10. Williamson, J.F., Coursey, B.M., DeWerd, L.A., Hanson, W.F., Nath, R., and Ibbott, G.: Guidance to Users of Nycomed Amersham and North American Scientific, Inc., I-125 Interstitial Sources: Dosimetry and Calibration Changes: Recommendations of the American Association of Physicists in Medicine Radiation Therapy Committee Ad Hoc Subcommittee on Low-Energy Seed Dosimetry. Med. Phys. 26(4):570-573, 1999.

11. Williamson, J.F., Coursey, B.M., DeWerd, L.A., Hanson, W.F., Nath, R., Rivard, M.J., and Ibbott, G.: Recommendations of the American Association of Physicists in Medicine on 103-Pd Interstitial Source Calibration and Dosimetry: Implications for Dose Specification and Prescription. Med. Phys. 27(4):634-642, 2000.

12. Nag, S, et al. American Brachytherapy Society (ABS) recommendations for transperineal permanent brachytherapy of prostate cancer, Int J Radiat Oncol Biol Phys, 44(4):789-799, 1999.

13. Nag, S, et al. The American Brachytherapy Society recommendations for permanent prostate brachytherapy postimplant dosimetric analysis, Int J Radiat Oncol Biol Phys, 46(1):221-230, 2000.

III. Credentialing

A. General: Brachytherapy, by its nature, is dependent upon the skill of the brachytherapist and the expertise of the support staff. Credentialing therefore needs to address the qualifications and efforts of the implant team as well as the type and quality of available equipment. A credentialing questionnaire is available via the 3D QA Center's web site (http://3dqa.wustl.edu/).

B. Equipment

1. Imaging: If ultrasound, fluoroscopy, CT or MRI is used to perform prostate implants, the institution is asked to explain how the imaging capability of the equipment was determined and what regularly scheduled procedures are in place to insure that the equipment continues to meet stated specifications.

2. Treatment Planning: Information pertaining to the system used for pre and post implant planning and evaluation is listed on the credentialing questionnaire. Capabilities and the use of the system in the conduct of the procedure should be detailed, as well as the routine QA tests performed to insure the proper functioning of the treatment planning system (TPS).

   The TPS must be able to perform structure-based analysis from axial image sets. This shall include isodose display and generation of Dose-Volume Histograms (DVHs).

   The calculation grid should be set no larger than (2mm x 2mm x the axial slice width).

   The TPS must be capable of transmitting data to the 3DQA Center electronically.

   The method of conducting a check of the calculations performed by the TPS must be provided.

3. Sources: The questionnaire queries the type, form and range of nominal strengths for sources used for prostate implantation. Additionally, the procedures used to insure the receipt and implantation of the proper sources (e.g., assay and handling procedures) must be provided. Assay procedures and regular quality control of the assay equipment will be addressed.

   Iodine-125 or Palladium-103 seeds may be used. The sources must be received and inventoried in accordance with state and federal regulations. At least 10% of the sources will be assayed in such a manner that direct traceability to either the NIST or an ADCL is maintained. NIST 1999 standards will be used. Agreement of the average measured source strength shall agree with that indicated in the vendor's calibration certificate to within $\pm$5%. No measured source strengths should fall outside $\pm$10% of that indicated in the vendor's calibration certificate.

4. Specific equipment standards
   a. Ultrasound (Frequencies, axial and lateral resolution, low contrast detectability, noise)
   b. Fluoroscopy (Resolution, contrast, noise, dose)
   c. CT (Resolution, contrast, noise, dose)
   d. MRI (Resolution, contrast, noise)
   e. Assay equipment
      (1) NIST-traceable calibration once every year either by an ADCL or a vendor-calibrated source.

(2) Sensitivity sufficient to distinguish differences of one part in 100.

(3) If the assay is to be used for calibration of sources as opposed to quality assurance (i.e., the assay source strength is used for planning, as opposed to that stated by the manufacturer), the system must meet the qualifications for a dose calibrator (e.g., linearity and reproducibility).

C. Procedures

1. Protocols: Written protocols that describe the implant procedure shall be attached to the questionnaire. These protocols should address, as a minimum, patient selection and flow, procedural scheduling and conduct, source procurement and handling, record keeping and safety procedures.

2. Design Methods: Implant design procedures will be addressed, whether the implants are individually designed prior to the implant or the implants are performed according to a set of rules developed for all cases and modified individually in the operating room. The method of delineating the gross tumor volume (GTV), the clinical target volume (CTV) and the planning target volume (PTV) needs to be provided as well as any regular deviations from the plan (e.g., the insertion of extra sources).

D. Individual Qualifications: The training and experience of the implant team is of paramount importance in the performance of a quality implant and is addressed in the questionnaire for the following individuals: radiation oncologist, urologist, medical physicist, dosimetrist, ultrasonographer, and any other personnel that the brachytherapist feels might materially affect the quality of the implant.

IV. Procedural Standards

A. The institution should have a written protocol outlining the normal conduct of the implant procedure. This protocol should address, as a minimum, order, receipt, inventory, handling and disposal of radioactive sources; patient selection, scheduling, and flow; procedural conduct and record keeping.

B. Treatment Volumes.

The *Clinical Target Volume* is to be specified by protocol. Typically it is the pre-implant TRUS definition of the prostate.

The *Planning Target Volume* is to be specified by protocol as an enlargement of the CTV by a specified amount in the lateral, anterior, posterior, cranial, and caudal directions.

The *Evaluation Target Volume* (ETV) is the post implant CT definition of the prostate.

B. Preplanning should be performed individually on a treatment planning system or via a standard, published implant rules (a nomogram with distribution rules, for instance). Prior to the beginning of the implant procedure, each member of the implant team must have access to the following written information: patient demographic data, disease specifics, size and location of the CTV and PTV, the type, strength, and number of sources that will be implanted and their planned location, the targeted dosimetric result of the implant, e.g., the reference dose and the design intent to deliver at least this dose to the PTV.

C. A method of independently checking the results of the pre-plan is required prior to performing the implant. Comparison with similar, previous implants via an institutionally developed gland size versus total air kerma strength curve is acceptable.

D. Post-Implant Dosimetric Analysis.

1. Post-Implant Treatment Plan: A CT scan will be preformed according to protocol following the implant. The patient will be scanned in a supine position. No contrast will be used. Abutting slices of 3 mm or less will be acquired from 2 cm cephalad to the base of the gland to 2 cm caudad to the apex. All of the seeds used in the implant should be encompassed in the scan. The ETV shall be determined from this scan, as shall the location of the urethra and the rectum. The CT scan will be used to create a post-implant treatment plan (post plan). A scout film or another radiograph that can be used to verify the number of sources will be taken.

2. Reporting: Guidelines established by the American Brachytherapy Society (IJROBP 46:221, 2000) are to be followed. DVH-based analysis must be used in the post-plan evaluation. The following values shall be reported. V_n is the percentage of the ETV that received at least n% of the prescription dose. D_m is the minimum dose received by m% of the ETV.
   - *Coverage.* V_{100}, V_{90}, V_{80}, D_{90}.
   - *Uniformity.* V_{150}.
   - *Urethra.* The maximum dose to the urethra and volume of urethra (in cm^3) that received more than 200% of the prescription dose.
   - *Rectum.* The maximum dose to the rectum and the volume of the rectum (in cm^3) that received more than 100% of the prescription dose.

V. Data to be Submitted to the 3D QA Center

A. A pre-implant treatment plan, if one is performed. The pre-implant treatment plan will consist of at least the following.

1. Hardcopies of the pre-implant TRUS images with CTV and PTV annotated.

2. Hard copy isodoses showing the PTV with isodose lines superimposed on the volume study image set will be provided for at least three transverse cuts (one each near the superior and inferior periphery of the CTV and one near the center) in such a fashion as to be able to determine the extent of the isodose surface and its relationship to the target and surrounding anatomy. Isodose lines may be normalized to some value (e.g., the reference dose) or displayed in dose, but will include at least the following values with relation to the prescription (reference) dose: 200%, 150%, 100%, 80%, and 50%

3. A copy of the physician's prescription.

B. A copy of the implant records will be provided showing the final number of sources implanted. The implant records must also reflect any deviation from either the pre-plan or, for those patients implanted with a nomogram and implant rules, the template locations, spacing and quantity of sources used for each needle. A copy of the film taken after the procedure.

C. A copy of the post-implant CT scan, ETV and organs at risk delineation and dosimetry calculations (submitted electronically in a 3D QA Center approved digital format). The post-implant treatment plan will consist of the following.

1. A copy of the CT scan used to create the post-implant treatment plan (post plan). Each submitted image set shall have the following structures delineated on each image, if applicable: ETV (Prostate), urethra, and rectum

2. A copy of the film or scout taken during the post implant CT.

3. Hard copy isodoses showing the ETV with isodose lines superimposed on the volume study image set will be provided for at least three transverse cuts (one each near the superior and inferior periphery of the ETV and one near the center) in such a fashion as to be able to determine the extent of the isodose surface and its relationship to the target and surrounding anatomy. Isodose lines may be normalized to some value (e.g., the reference dose) or displayed in dose, but will include at least the following values with relation to the prescription (reference) dose: 200%, 150%, 100%, 80%, 50%

4. The seed localization information must be submitted in a 3D QA Center approved digital format.

5. Dose volume histogram showing the distribution of dose within the ETV (Prostate).

6. A copy of the post implant dosimetry report that contains the information required in paragraph IV.D.2 above.

VI. Centralized Quality Assurance Review

A. Quality Assurance of Digital Data Format and Volumetric-Image Scan Data

1. The format of the digital TPV data submitted will be reviewed for compliance with the appropriate exchange specification version. Deviations from compliance will be noted and, depending upon the severity of the deviation, may require a complete resubmission of the digital data set.

2. The volumetric image data set is reviewed to ensure protocol compliance with regard to both interslice spacing as well as the superior/inferior extents of the scan region.

B. Quality Assurance of Target Volumes and Organs at Risk Volumes

1. The contours of the CTV, PTV, ETV, and designated organs at risk (urethra, rectum) will be reviewed for the first 5 cases submitted by each institution.

2. After institution has demonstrated compliance with protocol, future cases may be spot checked only.

C. Quality Assurance of the Dose Distribution

1. The digital dose distribution will be displayed as isodoses overlaid on selected slices of the image data set and compared with hardcopy isodose distributions for the plans submitted in order to verify correct interpretation and conversion of the digital patient and dose data.

2. The 3-D QA Center will calculate DVH's for the dose distributions submitted. They may be compared them with the digitally submitted DVHs for the ETV and designated organs at risk.

D. Evaluation Criteria

1. No variation: D_{90} for the ETV is greater than the prescription dose but less than 130% of the prescription dose.

2. Minor Variation: D_{90} for the ETV is greater than 90% of the prescription dose, but less than the prescription dose, or greater than 130% of the prescription dose.
3. Major Variation: D_{90} for the ETV is less than 90% of the prescription dose.

Proceedings of the XIIIth International Conference on The Use of Computers in Radiation Therapy, May 22-25, 2000, Heidelberg, Germany, edited by W. Schlegel and T. Bortfelt, 483-485, 2000.

Database infrastructure for multi-institutional clinical trials in 3D conformal radiotherapy and prostate brachytherapy

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Introduction

The practice of three-dimensional conformal radiation therapy (3DCRT) is heavily dependent on the use of image, geometric, and dosimetric data for treatment planning and verification. Several Radiation Therapy Oncology Group (RTOG) multi-institutional clinical protocols involving relationships of radiation dose and response in 3DCRT have been designed to acquire and collect both these treatment planning and verification (TPV) data as well as clinical endpoints. These TPV data have been evaluated by the 3DQA Center at Washington University in an effort (a) to evaluate the consistency of data and (b) to establish a database which can be linked to clinical outcomes for evaluating response statistics and developing dose-response models. To address these aims, two databases have been developed in the 3DQA Center. The first is a quality-assurance process-tracking database, the second a repository for evaluated TPV data for protocol cases.

Material and methods

QA Process Database

TPV data for three ongoing RTOG 3DCRT clinical trials are submitted to the 3DQA Center via internet FTP transfers or tape cartridges[1]. When these data are received, they are examined using a 3D radiotherapy treatment planning and review system (RTPRS) and its associated software tools. Submitted data are evaluated for completeness and consistency with protocol requirements. This QA process involves evaluation and scoring of CT scan coverage, target and organ contours, radiation field shape and placement, dose prescription, and dose uniformity.

Treatment Planning and Verification Database

Once TPV data submitted by participating institutions have been evaluated and scored in the 3DQA Center, they are loaded into a second database which serves as a repository for this data and a means for correlation of treatment planning information with clinical outcomes. Information obtained in the QA evaluation process and stored in the QA Process database are used to facilitate the loading of TPV data into the data repository. Besides tracking the progress of evaluation and indicating readiness of data for loading, the QA Process database identifies initial, boost, and composite treatment plans in the RTPRS with data to be loaded.

Data Model

The database schemas for the QA Process and TPV databases were developed using an entity-relationship model[2]. The data model used for the QA Process database consists of two main sets of entities. The first and most important set of entities are identified by a particular patient data set or "protocol case" and describe some feature of the data or QA evaluation for that case. Entities in this set include those describing

- the timeliness and completeness of data submitted to the QA center,
- QA scores for organ/target volume definition, field shaping and placement,
- dosimetric analysis for normal structures (total volume; prescription, maximum, and mean doses; and percent of volume receiving ≥ $TD_{5/5}$ dose),
- dosimetric analysis for target volumes (total volume; prescription, ICRU reference, maximum, minimum, and mean doses; percentage of volume receiving ≥ prescription dose; and target coverage score),
- dose heterogeneity and conformity indices for target volumes,
- dates on which each fraction group was treated,
- a record of dates on which various portions of the case review were completed and the individuals responsible for each portion,
- a log of problems identified in the format or content of submitted data and their resolutions, and
- identification of tape volumes containing backup copies of submitted data.

A second set of entities are identified by institutions submitting data to the QA center. Entities in this set describe

- the credential status of institutions and date on which this status last changed and
- contact information for individuals in participating institutions.

The entities described above correspond directly to tables in the relational database implementation. Several additional tables are used as dictionaries for lookup of protocol-specific information including prescription dose levels, stratification groups, target volumes, organs at risk, and QA scoring definitions. Other tables are used to identify compatible versions of user interface programs and generate unique identifiers ("surrogate keys") for database tables.

The database schemas for QA Process and TPV databases were designed from the outset to support multiple protocols. Small changes in these schemas have been made as the QA process itself has matured, but no major, protocol-specific alteration has been required for new 3DCRT external beam studies. However, development of support for prostate brachytherapy protocols is prompting an update of TPV data submission methods (RTOG Data Exchange Format) and of the TPV database to include brachytherapy source specifications and new imaging modalities (MR and US).

The data model for the TPV database was originally conceived as including both patient imaging and treatment planning data as well as clinical outcomes contained on protocol forms. It has since become clear that maintaining both TPV and primary clinical data in a single database is not a practical goal because the quality assurance processes for TPV and clinical data are best carried out separately by the respective physics and statistical centers. Thus, effort has shifted to maintaining the TPV and clinical data subsets in separate databases maintained by the organizations responsible for assuring the quality of the data.

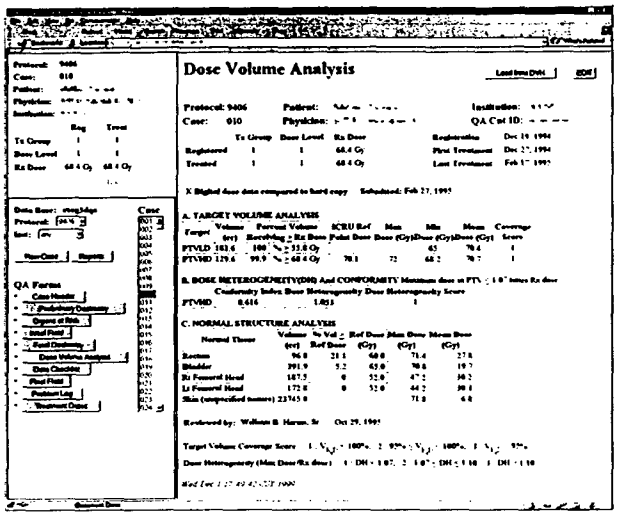

Figure 1: WWW-based user interface for QA Process database

The correlation of dose information (TPV data subset) with response (clinical data subset) requires access to both of these components. With these components stored in two separate (and geographically remote) database systems, both are needed to satisfy queries related to dose and response. Thus, some method must be used to link them. This linkage can be accomplished either by replication of data from one database to the other, or by accessing both databases to satisfy user queries.

Replication of data between database systems allows users to pose queries related to either or both TPV and clinical components within a single database system. This approach has been implemented in the 3DQA Center for data obtained in one protocol study. Queries are based on a single data model incorporating both TPV data and a replicated portion of clinical data supplied by the RTOG statistical support center. Data are copied between systems and updated through the exchange of text files.

Accessing two separate databases requires users to structure queries as two separate sub-queries, one restricted to TPV data, the other to clinical data. Fortunately, many questions related to dose and response are naturally structured as a partitioning of protocol cases based on one subset of the data (e.g., dose) and an evaluation of some parameter in the other subset (e.g., occurrence of some complication) for each group in this partition. While the widespread implementation of the open database connectivity (ODBC) interface makes such implementations possible, this approach requires knowledge of two different database schemas and access permission for two distinct systems maintained by two separate quality assurance entities.

Internal Access to Database

A web-browser interface has been developed to provide access to the QA process database for review and editing of protocol case QA scores and status information within the 3DQA Center. This interface has been realized using HTML frames as seen in the example screen shown in Figure 1. The user selects a protocol study and a case number within the study in the lower left hand frame. Ten buttons in this frame are used to display various QA forms for the selected case in the large, right hand frame. The small frame in the upper left hand corner displays basic information about the selected case including the patient name, physician name, submitting institution, as well as the dose level, stratification group, and prescription dose for the case. Along the bottom of this frame are codes which indicate which QA review forms are yet to be completed. When a QA form is selected, the relevant information for that case currently resident in the QA process database is displayed. This "browse" mode display can be printed using the print command of the web browser. An "edit" button in the top right-hand corner of this frame causes the "browse" display to be replaced by an "edit" display with editable fields containing the current information. The user can make changes to existing values or enter new values in these fields. A "Save" button on the edit page commits changes to the database, a "cancel" button returns to the "browse" page without updating the database, and a "reset" button resets editable fields to reflect the current contents of the database.

External Access to Database

Protocol participants can obtain feedback regarding the status and QA scores of cases they have submitted by accessing this information via the 3DQA Center web server (http://rtog3dqa.wustl.edu). This interface allows users with assigned passwords to view several QA forms, logs of unresolved problems, and a checklist of submitted data for protocol cases they have submitted to the 3D QA Center.

Participants can also submit protocol T2 (Digital Patient Submission Information) Forms for their protocol cases or dry run submissions online using an HTML-forms-based web interface. Online T2 forms are printed in the 3D QA Center and delivered via email to QA center personnel.

As the number of supported study protocols expands, the need to involve physicians at remote sites in the QA process grows, as does the importance of tools for remote review of submitted TPV data. By eliminating the need to distribute and configure software applications at remote sites, the ubiquitous web-browser interface greatly simplifies the deployment of remote review tools. Image-based tools are being developed to evaluate target-volume and critical-structure definitions as well as portal shape and placement. A web-based CT image review tool displays organ and target-volume contours on selected CT image slices. Treatment verification images can be reviewed

using the Web View-Box tool, which displays pairs of pre-aligned simulation (or DRR) and portal images.

Web Server Database Connectivity

The architecture used implementing web-based access tools is shown schematically in figure 2. These tools have been realized using PERL-language CGI scripts performing database query and update functions as well as the formatting of retrieved information. Image formatting utilities are invoked by the CGI script to generate GIF and/or JPEG images for inclusion in HTML documents. Using such a utility, data retrieved from the database can be used to annotate images, e.g., for drawing organ contours or isodose curves on CT images or portal apertures on treatment verification images.

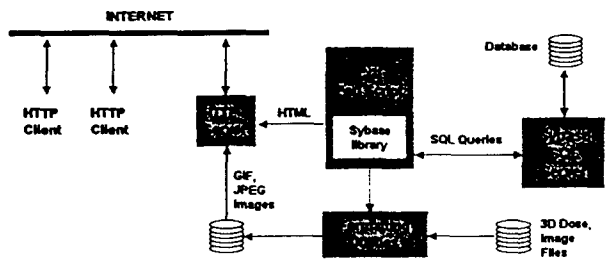

Figure 2: WWW-server architecture

Results and discussion

The process of preparing data for loading into the TPV database has exposed several issues including the preservation of patient anonymity and the standardization of target-volume and organ identifiers.

Anonymization and Confidentiality

While it is possible (and helpful) to retain the identity of patients, physicians, and submitting institutions in the QA process database, such information must be withheld when providing access to TPV data. In contrast to the QA process database, the TPV database contains no explicit patient identification. Thus, guarding confidentiality is largely a matter of preventing inappropriate access to the QA process database. An important exception is the annotation written on digital films. Names of patients, physicians and institutions on these images must be made illegible before they can be loaded into the database. A web-based interface is currently used to "anonymize" submitted films in the 3D QA Center. The user identifies regions of the image which contain confidential identification by clicking on vertices of polygonal boundaries around these areas. Once identified, these regions are "pixelated" by replacing pixels in 8x8-pixel squares by the average value of the pixels they contain.

Dual-use Data

Three considerations make it attractive to use the same image/dose data files for both database and 3D RTPRS access. First, these data are large and dominate storage requirements for TPV data. Second, once the QA review has been completed, these data do not change. Third, while these image data may be retrieved for later study, there is at present no meaningful way to construct queries based on their content. Consequently, image and dose distributions have been stored in data files outside the database.

Standardization of Structure Identifiers

In order to compare dosimetric data for organ and target volumes in multiple cases of a protocol, the comparable volumes must be identified in the same way for each case in the database. While the RTOG 3DCRT protocols specify which organs and target volumes must be defined, there is considerable variability in the names used by protocol participants to identify the same volumes. Before being loaded into the TPV database, user-supplied organ and target-volume names in submitted data sets must be mapped to standard identifiers using software developed in the 3D QA Center.

Conclusion

The development of a database infrastructure to support quality assurance in multi-institutional 3DCRT trials has been described. Segregation of data into a QA process database (dynamic) and TPV database (archival) simplifies the protection of confidential information. Patient confidentiality and data standardization issues must be addressed as part of the QA process. Web-based database tools are an essential part of the 3DQA center information infrastructure. Web-based access to provide feedback of QA information to participants has proven useful. Web-based QA review tools have the potential to allow physician review remote from the 3DQA Center.

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[1] Harms, W B, Bosch, W R, and Purdy J A 1997 An interim digital data exchange standard for multi-institutional 3D conformal radiation therapy trials *XII International Conference on the Use of Computers in Radiation Therapy*, D D Leavitt and G Starkschall eds. 465-468

[2] Bosch W R, Lakanen T L, Kahn M G, Harms W B, and Purdy J A 1997 An image/clinical database for multi-institutional clinical trials in 3D conformal radiation therapy *XII International Conference on the Use of Computers in Radiation Therapy*, D D Leavitt and G Starkschall eds. 455-457

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Digital data exchange for multi-institutional clinical trials in 3D conformal radiation therapy and prostate brachytherapy

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Introduction

The 3D Quality Assurance (3DQA) Center was established at the Washington University School of Medicine in 1992 to provide quality control for multi-institutional 3D conformal radiation therapy (3DCRT) clinical trials being developed by the Radiation Therapy Oncology Group (RTOG). One of the challenges this presented was how to acquire the patient image, geometric, and dosimetric data 3DCRT protocols generated. At the previous ICCR meeting we presented a standard for the submission of digital data to the 3DQA Center for review [1]. We now present changes to the standard since the previous presentation and discuss the 3DQA Center's plan for migrating to the use of DICOM 3.0, which now includes RT objects, for digital data submission. More information can be obtained from our prior presentation [1] or from the 3DQA Center's web page [2]. Briefly, a data exchange submission consists of a set of files. The first file in the file set is a "directory file" describing all of the other "data files". The directory file consists of keyword and keyvalue pairs describing the data files contained in the submission.

Material and methods

Description of data submission

Figure 1 shows a block diagram of the process of preparing a submission of a protocol data set to the RTOG 3DQA Center. The first step is to obtain from the user (typically a dosimetrist or physicist) a specification of all the data to be included in the submission. We recognize that electronic data submission is laborious in the current implementation on most image-based planning systems. Continued work in the area of data exchange by the treatment planning system manufacturers is needed, and users are encouraged to contact the manufacturer of their treatment planning system and request improved system features that will simplify the data submission process. For example, a utility such as the graphical user interface (GUI) shown in Figure 2 that was designed and implemented by

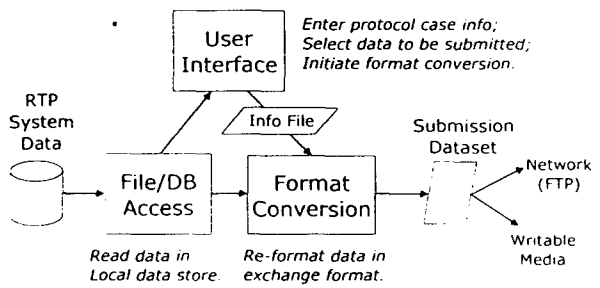

Figure 1: Block Diagram of Data Submission.

3DQA Center staff could be provided that would allow the user to pre-select the data required for submission specific to the 3DCRT protocol. This utility would in turn create a button (or

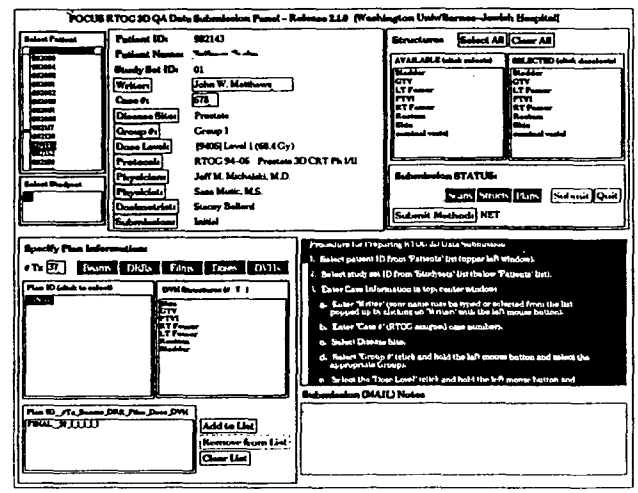

Figure 2: An example of the Graphical User Interface (GUI) used to aid correct and easy data submission.

at most only a few buttons) on a GUI for submitting data. When clicked on, the protocol data would automatically be selected and sent to the 3DQA Center. All of the additional edit features shown in our prototype GUI would be used only for exceptional submissions such as those correcting contour or planning problems in earlier submissions for the same patient in order to reduce the amount of data requiring resubmission. Currently, the GUI requires a dosimetrist to first select a patient ID and study-set. The interface then shows the data available for the selected patient study-set including CT scans, anatomical structures and treatment target volumes, and therapy plans. The individual submitting the data must input the RTOG case number, therapy protocol and stratification group number, treatment site, dose level, and physician, physicist, and dosimetrist involved with the protocol case. For therapy plans selected for submission, the GUI requires further selection of plan data to be submitted including beam or seed geometry, dose distributions, Digital Reconstructed Radiographs (DRRs), plan verification films, and DVHs. Clearly, new features are needed on treatment planning systems that make the submission process easier and also help in enforcing complete and correct protocol submission.

Under the current system, when the user is finished selecting data to be submitted, a button on the GUI initiates the submission process. The first step in this process is the generation of an "info" file . The info file is a short text file that specifies all the data that will be submitted; the info file is read by low level software that can access the treatment

planning data of the treatment planning system and convert the appropriate data into the RTOG data exchange format files. Once converted the data are either written to a magnetic tape that is sent to the RTOG 3D QA Center, or more typically sent directly to the QA Center via the FTP protocol over the internet. The info file format has been augmented to include Brachytherapy Seed plan data objects as well as Ultrasound images. The format of the info file is shown in Figure 3.

Data processing statistics

As of 10 December 1999, the 3DQA Center has processed 918 patient 3DCRT data sets. The processed data occupies 60 Gigabytes of storage. The network submission of data requires from a few minutes to about one hour depending on network performance for a given connection (depends both on peak bandwidth of the path and network traffic). Processing of a case at the 3DQA Center takes about two hours for a "clean

```
**********
RTOG Case Number
Institution
Writer
Patient ID
Patient Name
Studyset ID
Site of Interest (Optional keyword for CT)
Number of Comment files
{Names of Comment files; one per line}
Number of CT files
{Names of CT files; one file name per line in descending order}
Number of MR files
{Names of MR files; one file name per line in descending order}
Number of US files
{Names of US files; one file name per line in descending order}
Number of anatomical/target structures
{Names of structures, one name per line}
Number of orphan films
{Name of orphan film file}
{Description of orphan film}
{repeat for each orphan film; two lines per film}
Number of Teletherapy plans
{Plan ID for 1st Teletherapy plan}
{Number of treatments for fraction group}
{Beam Geometry Flag}
{DRR Flag}
{Dose Flag}
{Number of beam "films"}
{File name of image}
{Beam number this image corresponds to}
{Beam description}
{repeat for each film; three lines per film}
{DVH File Name}
{repeat for each Teletherapy plan}
Number of Brachytherapy Seed plans
{Plan ID for 1st Brachytherapy Seed plan}
{Seed Geometry Flag}
{Dose Flag}
{DVH File Name}
{repeat for each Brachytherapy Seed plan}

{} indicates lines that appear only as necessary
```

Figure 3: Description of the "info" file which controls the generation of Data Exchange submission.

case", i.e., all data are correctly submitted and the protocol is correctly followed. If there are errors, the case is scored but then corrections are made before the data are entered in the database [3]; this typically may take several days.

Results and discussion

Data processing for case submission

If the "Format Conversion" process in Figure 1 is structured properly, then the job of migrating to DICOM for data exchange can be more easily accomplished. The collection of data from the local RTP system is inherently vendor specific; while the reformatting of data into data exchange specified format is vendor independent. Segregating the code as much as possible gives two advantages: 1) writing RTOG data exchange format files is RTP system independent and can be reused by multiple vendors; 2) the output portion of the process could be rewritten to implement DICOM while preserving the data collection portions of the code. Example "C" code which indicates the requirements for RTP system data collection and implements output of the RTOG data exchange format is posted on the 3DQA Center web page [2].

Data processing for permanent prostate implants

The RTOG 3DQA Center is currently adding the capability of supporting protocols for Transperineal Interstitial Permanent Prostate Brachytherapy (TIPPB). The additional data types needed to support these protocols are: ultrasound (US) images, MR images, and brachytherapy seed plans. US images and MR images data exchange issues are very similar to those posed by the already implemented CT image data exchange and thus will not be described here. The "Seed Plan" data type adds the following directory keywords: SEED MODEL, ISOTOPE, SEED STRENGTH, STRENGTH UNITS, DATE OF IMPLANT, and NUMBER OF SEEDS. The data file for "Seed Plan" consists of the spatial coordinates of the seeds. The RTOG 3DQA Center is now able to read TIPPB plans and we expect that multi-institutional protocol(s) will be developed shortly.

Date exchange workshops

The 3DQA Center has held two workshops on the implementation of RTOG data exchange. The first workshop was held in March 1995 and was intended primarily for the original nine members of the RTOG 94-06 prostate dose escalation protocol. However the workshop was attended by the following RTP system vendors: ADAC, CMS, PTI, and Rahd. The second workshop was held in September 1999 and was attended by the following RTP system vendors: CMS, Elekta/PTI, Prowess/SSGI, and Varian/MMS. At the second workshop the RTOG data exchange specification including TIPPB objects (version 4.00) was finalized and the participants also discussed the future use of DICOM for data submission.

DICOM for data submission

The 3DQA Center is committed to implementing the ability to receive DICOM data submissions within the next year. DICOM 3.0 now includes RT objects: RT image, RT dose, RT structure set, RT plan, RT beams treatment record, RT brachy

treatment record, and RT treatment summary record. The usefulness of DICOM for submission of protocol data, however, depends on the extent to which RTP system manufacturers implement DICOM export mechanisms for all of the data objects needed for a complete protocol submission.

The first step for the 3DQA Center is to provide an Application Profile for DICOM data submission. A DICOM Application Profile defines a selection of choices at the various layers of the DICOM standard which are applicable to a specific need or context in which the standard is intended to be used. For the submission of data to the 3DQA Center, this profile indicates

- which DICOM information objects and associated service-object pair (SOP) classes will be used for protocol submissions and which are optional;
- the selection of a specific Media Format definition (from DICOM Part 12) including the selected Physical Medium, a specific associated Media Format and the mapping of this Media Format (or file system) services onto the DICOM File Service;
- the selection of appropriate Transfer Syntaxes; and
- other choices facilitating interoperability such as specific limits (e.g., maximum file sizes, if necessary, support of options, if any).

One model for conversion to a DICOM based submission process makes use of DICOM Part 10 file-set specification. In a manner similar to the RTOG data exchange, DICOM information objects are encoded as files on physical media (disk or tape) with a DICOMDIR directory file describing the contents of the file-set. The recordable compact disc (CDR) is an attractive physical medium for protocol data submissions. A DICOM media storage model already exists for CDR using the ISO 9660 file system. This medium is inexpensive, small, and fairly rugged; its capacity (approximately 700 megabytes) is sufficient for the foreseeable future in terms of the data required for a single case. A CDR disk can be shipped to the 3DQA Center by mail or overnight delivery and the CDR itself serves as an archive of the submitted data (submitted data are currently archived to magneto-optic disks).

In addition to submission of DICOM Part 10 files using physical media, these file-sets can be transferred to the 3DQA Center over the Internet using FTP. While this method of exchange is not specified by the DICOM standard, binary-mode FTP transfers of properly encoded DICOM file-sets would work.

Conclusion

The RTOG data exchange specification has been extended to include support for TIPPB protocols. However, the RTOG data exchange specification is clearly an interim standard. It is understood that it has a limited lifetime. This standard will ultimately be replaced by the RT information objects of DICOM 3.0 which themselves were motivated in part by this interim standard. However, this replacement must await the implementation of the RT information objects and their support by both commercial 3-D treatment planning companies and the 3DQA Center. The uncertainty of a time frame for broad acceptance and implementation of the DICOM RT objects (and because of the wider commercial implementation of the RTOG data exchange specification) suggests that it will continue to play an important role in support of 3DCRT multi-institutional trials for several more years.

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[1] Harms, W B, Bosch, W R, and Purdy J A 1997 An interim digital data exchange standard for multi-institutional 3D conformal radiation therapy trials *XII international conference on the use of computers in radiation therapy*, D D Leavitt and G Starkschall eds. 465-468

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APPENDIX 6: List of Personnel who Contributed to Grant.

Name	Degree(s)	Role on Project *(e. g. PI, Res. Assoc.)*
Purdy, James A.	Ph.D.	Principal Investigator
Bosch, Walter R.	D.Sc.	Computer Scientist
Harms, William B.	B.S.	Medical Physicist
Matthews, John W.	D.Sc.	Computer Scientist

DEPARTMENT OF THE ARMY
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